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(54) **Intravascular imaging guide wire apparatus and methods for use and manufacture.**

(57) A device for ultrasonic imaging, and methods for the use and manufacture thereof, particularly of small coronary vessels comprises an elongate member with a distal end that can be positioned within a small vessel of a patient's body while a proximal end is located outside the body, a transducer located at a distal end of the elongate member and operable to scan the distal coronary vessels with ultrasonic pulses, and a signal processor connected to a proximal end of the elongate member and to the transducer for generating and receiving pulses to and from the transducer. A motor may also be connected to the proximal end of the elongate member for rotating the transducer.

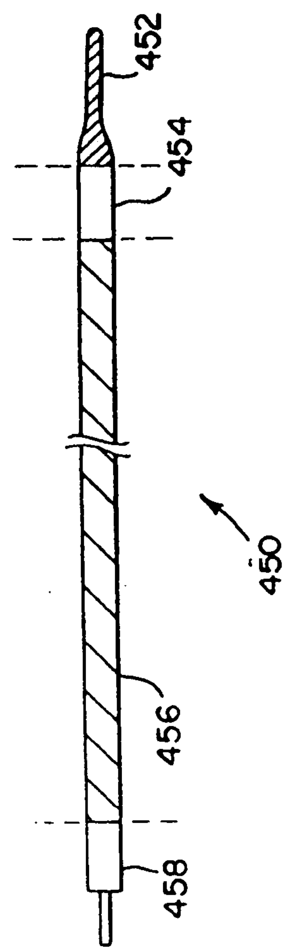

FIG. 1

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This invention relates to an ultrasonic imaging device and methods for use and manufacture thereof, and particularly to an ultrasonic imaging guide wire device positionable in coronary vessels to obtain images thereof.

Ultrasonic imaging of portions of a patient's body provides a useful tool in various areas of medical practice for determining the best type and course of treatment. Imaging of the coronary vessels of a patient by ultrasonic techniques could provide physicians with valuable information about the extent of a stenosis in the patient and help in determining whether procedures such as angioplasty or atherectomy are indicated or whether more invasive procedures may be warranted. However, obtaining ultrasonic images of the distal coronary vessels with sufficiently high resolution to be valuable for making medical decisions, such as described above, requires overcoming several significant obstacles one of the most significant of which relates to the size of the ultrasonic sensing device.

Obtaining ultrasonic images of high resolution of a body organ generally requires bringing an ultrasonic sensor (i.e. a transmitter/receiver) sufficiently proximate to the organ and scanning the organ with ultrasonic pulses. Ultrasonic imaging of organs deep within the body that are surrounded by other, relatively dense organs and tissues requires connecting a sensor on a probe and positioning the sensor and the probe near or even into the organ. The heart and the vessels connected to it are organs of this type. Because it is a well known technique to insert catheters, guide wires and probes into the coronary vasculature from remote sites via arteries, such as the femoral artery, and further because some of the information of interest to the physician is the extent of stenosis on the inside walls of the coronary vessels, it would be desirable to be able to position an ultrasonic sensor connected to a probe into the distal regions of the coronary vasculature via a remote arterial site, such as the femoral artery, to obtain ultrasonic images of the coronary arterial walls.

The vessels in the distal regions of the vascular tract that would be useful to image include the coronary arteries, branch vessels stemming from the external carotid artery such as the occipital and the arteries leading to the vessels of the head and brain, splenic, and the inferior mesenteric and renal arteries leading to the organs of the thorax. To be positioned in these regions, the size of an ultrasonic sensor and probe must be relatively small not just to traverse the arterial vessel but also to avoid occluding the vessel lumen. When a device, such as a catheter, probe, or sensor, is positioned in a blood vessel, it occupies a volume which restricts blood flow within the vessel as well as in vessels proximate thereto. When a device is positioned within an arterial vessel, the blood flow through the vessel is restricted to an annular region (i.e. the area of "ring"-shaped cross section) which is effectively created between the outer perimeter of the device and the inner wall of the vessel. This would normally not present a problem in large arteries with large blood flows, such as the femoral arteries of the legs, or the aorta, or in very proximal coronary arteries. In these large arteries, any restriction caused by the device would be relatively small and the blood flow would be relatively large. However, in small arteries in remote locations, such as the occipital that leads to the brain, or the coronary arteries of sizes of 3.0 mm or less that lead to the right and left sides of the heart, any restriction of blood flow must be minimized. The consequences of occluding these small vessels can cause a loss of flow in the coronary arteries of the heart which may have several adverse effects, such as severe chest pains, or physiological changes such as arrhythmia, ischemia, and tachycardiac response. These effects may be threatening to the patient and further, once begun, may be difficult to stabilize.

Moreover, not only are these latter vessels very small but these vessels are also those in which there might also be restrictive disorders, such as atherosclerosis. Atherosclerotic disease as well as other thrombus formations which occlude blood flow occurs in these smaller arteries due to the hemodynamics of the blood tissue interface. Reflecting this fact is that presently angioplasty is primarily performed in vessels of a size range of 2.0 to 3.5 mm in diameter. Such disorders would diminish the cross sectional area of these vessel lumens even more.

Therefore, a significant obstacle to using an intravascular probe device to obtain ultrasonic images of such vessels is that the probe should be sufficiently small in dimension so as not only to be positioned in these small, possibly partially occluded arteries, but also to be sufficiently small so as not to totally or almost totally occlude the lumen of the vessel into which it is positioned. Accordingly, for an ultrasonic sensor device to be used for distal coronary applications, it must be small enough to be suitably positioned in the coronary vessels and to permit a sufficient blood flow therearound. A guide wire function is to navigate to a location of interest in a patient's vasculature and to position a catheter over the guide wire into place for a procedure, such as balloon angioplasty. Because it would be desirable to have a device that would image the artery before, during and after such procedures, it would be advantageous to combine the functions of the guide wire and the imaging device. Most catheters are of a coaxial design so that once the catheter is in place the guide wire could be withdrawn and an imaging guide wire put in its place. Currently guide wires are used in dimensions of 0.018 inch or smaller.

The present invention provides a device for intravascular ultrasonic imaging, and methods for the use and

manufacture thereof, comprising an elongate member with a distal end that can be positioned within a vessel of a patient's body via a guide wire lumen of a conventional catheter. The device also includes a transducer located at a distal end of the elongate member and a signal processor connected to a proximal end of the elongate member for generating pulses to and receiving from said transducer. The device preferably includes a motor for rotating the transducer and a drive cable for connecting the transducer to the motor and the signal processor. The drive cable is operable to transmit electrical signals to and from the transducer.

In the drawings:

Figure 1 is a side elevational view of a first preferred embodiment of an imaging guide wire.

Figure 2 is a side elevational view of a preferred embodiment of a sliced transducer sensor for use in the imaging guide wire of Figure 1.

Figure 2a is a cross sectional view of the sliced transducer sensor of Figure 2 along lines 35A-35A.

Figure 3 is a top view of the sliced transducer sensor of Figures 2 and 2a.

Figures 4, 5, and 6 each show a top view of alternative constructions of the sliced transducer sensor of Figures 2 and 2a.

Figure 7 is a side elevational view of the preferred embodiment of the transducer sensor for use in the imaging guide wire of Figure 1 incorporating a sheath over the transducer sensor.

Figure 7a is a cross sectional view along line 40A - A' of the transducer sensor of Figure 7.

Figure 8 is a side elevational view of an alternative embodiment of the transducer sensor for use in the imaging guide wire of Figure 1 incorporating an exponential matching layer.

Figure 8a is a cross sectional view along line 41A - A' of the transducer sensor of Figure 8.

Figure 9 is a side elevational view of a preferred embodiment of the transducer sensor for use in the imaging guide wire of Figure 1 incorporating a formed sheath matching layer.

Figure 9a is a cross sectional view along line 42A - A' of the transducer sensor of Figure 9.

Figure 10 is a side elevational view of an embodiment of the transducer sensor for use in the imaging guide wire of Figure 1 incorporating a splined attenuation backing support.

Figure 10a is a cross sectional view along line 43A - A' of the transducer sensor of Figure 10.

Figure 11 is a side elevational view of an embodiment of a wedge transducer sensor for use in the imaging guide wire of Figure 1.

Figure 11a is a cross sectional view along line 44A - A' of the transducer sensor of Figure 11.

Figure 12 is a side elevational view of an embodiment of a multiple transducer sensor for use in the imaging guide wire of Figure 1.

Figure 12a is a cross sectional view along line 45A - A' of the transducer sensor of Figure 12.

Figure 13 is a side elevational view of an embodiment of the distal tip construction of the imaging guide wire of Figure 1.

Figure 14 is a side elevational view of an alternative embodiment of the distal tip construction of the imaging guide wire of Figure 1 incorporating a locking tip feature.

Figure 15 is a perspective view, partially disassembled, of an embodiment of the drive cable construction of the imaging guide wire of Figure 1.

Figures 16, 17, and 18 each show a perspective view of alternative embodiments of the proximal end section of the imaging guide wire of Figure 1.

Figure 19 is a side elevational view of an extension wire for use with the imaging guide wire of Figure 1.

Figure 20 is a side sectional view of a drive interface for making the electrical an mechanical connections for driving the imaging guide wire of Figure 1.

Figures 21a and 21b each show alternative embodiments of supporting means for the proximal end section of the imaging guide wire of Figure 1.

Figure 22 is a side sectional view of a holder apparatus for the imaging guide wire of Figure 1.

Figure 23 is a flow chart representing an embodiment of the pipeline architecture for the imager of Figure 1.

Figure 24 is a side sectional view of an alternative embodiment of the slip ring assembly incorporating a capacitive non-contacting slip ring assembly.

Figure 25 is a side sectional view of an alternative embodiment of the slip ring assembly incorporating a magnetic non-contacting slip ring assembly.

Figure 26 is a side sectional view of an alternative embodiment of the imager of Figure 1 incorporating an EEPROM into the imager to store essential product information.

Figure 27 is a perspective view of an embodiment of a cath lab patient table and accessories for use with the imager of Figure 1.

Figure 28 is plan view of yet another embodiment of the sensor housing of the present invention.

Figure 29 is plan view of still another embodiment of the sensor housing of the present invention.

Figure 30 is plan view of another embodiment of the present invention for 3-D imaging.

Figure 31 is a view of a distal section of an alternative embodiment of the elongate member with variations represented for 3-D indexing.

Figure 32 is a cross sectional view of the embodiment shown in Figure 31 along lines A - A'.

Figure 33 is a block diagram of the data and graphics pipeline of an alternative embodiment of the present invention.

A. Imaging Guide Wire

1. General Construction

An embodiment of the present invention may combine the functions of a guide wire with those of an ultrasonic imager.

The imaging guide wire, as described herein, is an intravascular imaging device having an ultrasonic sensor located at a distal end of an intravascular wire sized and adapted to be located within the guide wire lumen of conventional catheters used for intravascular procedures. As such, the imaging guide wire has several significant advantages. For example, the imaging guide wire can utilize the path provided by the guide wire lumen of a conventional catheter to image at the arterial location to which the catheter is advanced. Moreover, in several embodiments, the imaging guide wire may be provided with conventional guide wire features, e.g. a floppy spring tip, to enable the imaging guide wire to be used as both a conventional guide wire for positioning an intravascular catheter as well as imaging features, e.g. a sensor, to enable imaging the intravascular regions accessible thereby.

In order to be utilized in the above described manner, an embodiment of the imaging guide wire 450 is provided, as shown in Figure 1. The imaging guide wire 450 includes a tip section 452, a sensor section 454, a drive cable section 456, and a proximal connector section 458. As mentioned above, an essential requirement for The imaging guide wire is that it possess an outer profile of a size that allows it to fit through a guide wire lumen in conventional interventional catheters. In catheters that use 0.018 inch guide wires, the guide wire lumen has a diameter typically in a range between 0.020 and 0.022 inch. The diameter of the proximal section 458 of the imaging guide wire 450 may be as large as 0.020 inches but the rest of the imaging guide wire should be not more than approximately 0.018 inch. For use with catheters designed with guide wire lumens of other sizes, relative adjustments in dimension apply.

2. Imaging Guide Wire Sensor

a. Image Resolution

The image resolution of the imaging guide wire is limited by the optics of the aperture of the ultrasonic sensor. For an unfocused transducer the resolution can be approximated by using the maximum between the angle of beam divergence and the aperture width. The formula approximating the resolution from angular beam spread is:

$$x = R * \lambda / A$$

where,

x = resolution

R = range for sensor face

λ = wavelength of ultrasound

A = aperture width

For intravascular imaging, the depth of field where the best resolution is desired is between 1 mm and 3 mm from the face of the transducer. The outer limit of useful information is out around 4 mm to 5 mm from the transducer face. With these constraints, a transducer should provide the best performance in this range. For a flat, unfocused transducer, a preferred transducer aperture width can be determined for a selected operating frequency. The analysis in Table 1 is an approximation of actual performance since beyond the near field the beam is uniform and approaches this constant diffraction angle as distances increase. This analysis is useful to get a coarse estimate of the expected resolution as a function of the independent variables.

Table 1 shows the resolution for apertures of 0.5 mm, 0.4 mm, and 0.35 mm for operation at 30 MHz. (A 0.5 mm aperture is disclosed in the first embodiment described above in which the overall device profile is on the order of 3 Fr). The data of Table 1 indicate that for a system that will image out to approximately 5 mm radius (the range necessary for coronary arteries, for example), the optics limit the aperture to about 0.35 mm (0.014 inch). It should be noted that the resolution is improved out to the radius of 4 mm by up to 30%.

A=0.35mm	A=0.5mm	A=0.4mm	
	x(mm)	x(mm)	x(mm)
R=1mm	0.5	0.4	0.35
R=2mm	0.5	0.4	0.35
R=3mm	0.5	0.4	0.43
R=4mm	0.5	0.5	0.57
R=5mm	0.5	0.63	0.71
R=6mm	0.6	0.75	0.86
R=7mm	0.7	0.88	1.0

Table 1 Sensor at 30 MHz operation

By increasing the frequency up to 40 MHz and utilizing a method for reducing the signal scatter from blood (as disclosed below), the resolution can be further increased in the area close to the sensor face. Moreover, the aperture size can be reduced. Table 2 shows the resolution for apertures of 0.5 mm, 0.4 mm, and 0.35 mm for operation at 40 MHz.

A=0.3mm	A=0.5mm	A=0.4mm		A=0.35m
	x(mm)	x(mm)	x(mm)	x(mm)
R=1mm	0.5	0.4	0.35	0.3
R=2mm	0.5	0.4	0.35	0.3
R=3mm	0.5	0.4	0.35	0.36
R=4mm	0.5	0.4	0.41	0.48
R=5mm	0.5	0.47	0.51	0.6
R=6mm	0.5	0.56	0.61	0.71
R=7mm	0.5	0.66	0.71	0.83

Table 2 Sensor at 40 MHz operation

Table 2 shows that for a system that will image to approximately a 5 mm radius, the optics limit the aperture to about 0.3 mm (0.012 inch). It should be noted that, compared to the 0.5 mm aperture, the resolution is improved out to the radius of 4 mm by up to 40%. The embodiments of the present invention for imaging guide wires relate in scale to this size.

The significance of a 0.3 mm (0.012 inch) transducer aperture size is that this allows the imaging guide wire to possess an 0.014 inch overall device profile. This allows an imaging guide wire to be used with conventional over-the-wire type catheters that use a conventional 0.014 inch guide wire.

There are two significant factors to be considered in providing an 0.014 imaging guide wire. These factors relate to signal scatter from blood and transducer design.

b. Imaging Guide Wire Transducer Design

It is essential to consider the design and performance of the transducer sensor as the wavelength width to length ratio is established in the range consistent with the optics requirements set forth above. With a transducer of the size required for an imaging guide wire, it can be difficult to properly match the impedance of the transducer sensor to the drive cable with available materials and at the required frequencies.

There are two well known methods to model transducer performance. The model used for thickness mode vibration is known as the KLM model (Krimholtz, Leedom, Matthaei). This model is useful for modeling thick-

ness mode transducers that are substantially clamped in the other dimensions. With a transducer of a size that can be used in an imaging guide wire, the width mode of oscillation and excitation is significant. This diminishes the accuracy of the KLM model when applied to a sensor used in an imaging guide. This also makes the operation of a sensor with this construction more difficult to work with. A rectangular sensor can be made so that only its width is a consideration, however, with a circular aperture all directions should be considered.

Along with width oscillation being a consideration, the energy coupling coefficient (kt2) decreases significantly as the clamped construction is compromised. The coupling coefficient effects the signal level and ringdown performance so it is advantageous to provide a material or mechanical configuration that will give as high a kt2 value as possible. This consideration must be reconciled with the contrary considerations for aperture size.

The other model and method of constructing transducers is based upon "phased array" considerations. This model can be similar to the model above used with clamped thickness mode if a complex loading impedance is used. With phased arrays, the width to thickness ratio (G=W/T) of each phase element is preferably within a range where G=0.1 to 2.0 for reasonable performance. A maximum value for kt2 is obtained within the range of G=0.5 to 0.8. Accordingly, a sensor comprised of several separate elements, similar to a phased array, can be advantageously utilized in an imaging guide wire.

Such a sensor 500 is illustrated in Figures 2 and 2A. The sensor 500 is sliced parallel to the longitudinal axis of the drive cable 352 (shown in Figure 1) thereby forming discreet transducer elements 502. To minimize the width resonance of the sensor 500, the impedance between the elements 502 should be kept as low as possible.

The electrical excitation for the sliced sensor 502 is similar to that of the sensor 42, described above, and unlike conventional phased array type transducers. In conventional phased array excitation devices, each phased array element is excited (and read) separately from the other elements and separate electrical leads are required for each element. A disadvantage of such conventional phased array sensors is that the number of separate, discreet leads for each element occupies a significant area thereby limiting the size to which the device can be reduced.

As shown in Figure 3, in one embodiment, the elements or slices 502 are excited across the thickness direction of the elements. Alternatively, the elements can be excited across the width of each element. In this embodiment, the thickness of the transducer 500 is limited and constrained. However, through use of the sliced transducer face, the effective width of the transducer can be increased for the capacitance calculation. This allows the transducer to be made with the overall physical dimensions required for an imaging guide wire but with an impedance matched properly to the other system components, e.g. the drive cable.

Alternative embodiments of the sliced transducer sensor are shown in Figures 4, 5 and 6 in which the sliced sensor 500 is adapted with a circular aperture. With a circular aperture, the slices can be formed as straight lines thus forming rectangular elements (Figure 4), circular concentric slices forming circular elements (Figure 5), or spiral slices forming spiral elements (Figure 6). A circular aperture can also be formed on a rectangular substrate by metallizing the areas required to make the circle area active. Piezoelectric material that is not metallized on both sides and electrically connected to the signal cable would not be active and would not effectively form part of the acoustic aperture. In any of the alternative embodiment geometries, the use of a sliced transducer provides the capability to properly match the impedance of the transducer to the rest of the system components. Thus, transducer size is not a limiting constraint at these dimensions.

c. Additional Matching and Backing Layer Embodiments

For a solid sensor in a larger imaging guide wire, it is preferred that the transducer is air backed and have double matching layers. Double matching layers allow more energy to be transferred out the front of the transducer and less out of the back. By correct selection of the impedance and thickness of the matching layers, an air backed sensor can produce a near ideal pulse. It is desirable to keep the energy out of the metal or composite sensor holder. This feature is obtained by reducing the contact area between the two surfaces.

For an embodiment in which a fluid is trapped or otherwise exposed to the sensor, it is preferred to keep any fluid or material out of the space between the surfaces of the sensor and the mount. These surfaces can be treated to increase the surface tension between the surrounding fluid and bottom surfaces of the sensor and the mount.

Another alternative embodiment for accomplishing this is illustrated in Figures 7 and 7a. In Figure 7, mounting tabs 508 are located over the transducer 356 to aid in mounting the transducer 356 in place. A protective sheath 510 is included to provide a non-traumatic outer surface. By having a smooth end section, a gap 511 is formed between the sensor face 512 and the outer sheath 510. This gap 511 is preferably filled with water. Alternatively, there are a number of materials that have the acoustic impedance of water and could be used

as substitute alternatives for filling of this gap, such as silicon oil, castor oil, and many other fluids. It is preferred that this material be biocompatible should a rupture occur. Alternatively, the space 511 can be filled with a solid material that has.nearly the same acoustic properties as water. Preferable materials include TPX, low density PE and silicon rubbers. Even though silicon rubbers have high attenuation they may be suitable.

A further alternative embodiment is illustrated in Figures 8 and 8a. Instead of a single, solid material over the sensor 356, an exponential matching layer 516 is provided and shaped into the circular form of the holder 354. The exponential matching layer 516 is preferably formed of a series of layers in which the impedance follows an exponential manner from one layer to another. This type of matching layer is capable of providing as near to ideal matching as can be realistically achievable.

A further alternative embodiment is illustrated in Figures 9 and 9a. Less ideal but still suitable matching can be provided by forming the sheath 510 in a shape having a surface 520 that fully or partially fills the space in front of the transducer 256 thereby additionally providing the function of the matching layer of the previous embodiment. This sheath 510 with the formed surface 520 may be shrunk down over the transducer section 356 providing for a non-filled sensor face. The active area of the transducer 356 should be limited to the flat area provided by the formed sheath 520. A formed sheath provides matching nearly as good as that of the exponential matching layers of the previous embodiment and may be easier to construct.

Energy that enters the sensor mount 354 should be minimized. By reducing the amount of energy that is coupled into the backing, there is a corresponding reduction in the amount of energy that can reflect back into the sensor. The contact area between the backing and the backing support is therefore kept to a minimum. The energy can further be reduced by limiting the energy that enters the backing support. As mentioned above, one method is to use a composite metal and rubber or epoxy. This metal is preferably sintered or powder in epoxy. Another way to attenuate the energy that enters the backing layer or support is to add a quarter wavelength spline structure 524 around the backing layer support as shown in Figures 10 and 10a.

d. Wedge Transducer

Another alternative embodiment for the transducer design in an imaging guide wire is shown in Figure 11. In this embodiment, the transducer is a wedge geometry transducer 530. Wedge transducers have been used in many industries to provide a broadband signal while coupling to a low acoustic impedance medium. The wedge transducer material has a high acoustic impedance so that the acoustic energy is more easily coupled into the material. A very good material for the PZT sensor and water interface is brass. This provides for a broadband pulse with a short ringdown. The angle between the wedge material and the transducer face material 531 causes two waves to be formed. One wave travels out of the wedge through the transducer face material 531 to the blood and artery being imaged. The other wave reflects off the face, stays inside the wedge and is attenuated so the sensor can see the return reflections from the forward wave. This attenuation can be obtained using a number of different techniques depending on the level of attenuation needed.

One readily provided and effective method to provide the necessary attenuation is to make the backing material 532 off that side the same impedance as the wedge material. A tungsten and rubber epoxy mixture can be used for this purpose. The mixture requires a large percentage of tungsten by weight to get the impedance high enough to match the wedge material. This mixture is highly attenuative and a thickness of only a few mills of material is sufficient for the needed attenuation. To add to the attenuation at the wedge backing B interface, a quarter wavelength grating surface 534 can be machined or etched into the wedge material. This grating surface 534 reduces reflection back into the wedge 530 sufficiently without the use of a backing material at that location. Any additional artifacts can be reduced or eliminated through the use of the calibrated waveform pulser, described above, or by canceling out the repetitive return signal electrically.

The wedge transducer geometry allows for making a transducer in a size necessary for use in an imaging guide wire or even smaller. The minimum size of a transducer formed with the wedge geometry would be limited by the optics of the aperture, as described above. The wedge geometry allows the use of nearly all the cross section diameter for acoustic aperture because the beam is bent to a small angle from perpendicular to the wedge front face. Another advantage of the wedge design is that it provides a mechanical structure needed to support the sensor and the guide wire tip. In this case this structure is an integral acoustical part of the transducer.

e. Techniques For the Reduction of the Scatter From Blood

As mentioned above, with an imaging guide wire the frequency of operation can be approximately 40 MHz. At the short wavelengths corresponding to this operating frequency, it is preferred to provide a means to account for scattering due to structures (e.g. particles) found in blood. In ultrasound imaging at such frequencies,

such scattering can obscure the difference between the blood and artery or disease. A Rayleigh scattering analysis that assumes spherical bodies fairly portrays the observed phenomena.

One means for addressing this concern is to use a vector averaging circuit to filter out the fast moving blood scattering return signal. The spatial frequency of the artery information is limited to twice the angle of the beam. In practice, it works best to sample about 25% faster than the maximum frequency. Faster sampling rates do not provide any more useful information about the artery. Multiple fast sampling in the 30 microsecond to 100 microsecond range provides information that can be used to average out noise, random pulses, and fast-changing information from the blood scattering. For broad band noise, the signal-to-noise ratio is increased by the square root of the sample number. For random pulses and the type of signal received from blood scattering, the reduction is proportional to the sample number. This would be less than proportional for very dense return signals since some may overlap.

Another way to reduce the scattering signal from blood is to use a double frequency transducer. Figure 12 illustrates an embodiment utilizing such a transducer. The transducer 356 includes a first sensor 540 and a second sensor 542 located one over the other. An additional layer may be needed between these two sensors to separate and isolate them into two relatively narrow bandwidth sensors. With this construction, both sensors 540 and 542 are pulsed at the same time and the return signals are frequency multiplexed into different frequency bands. These frequency bands are separated with analog or digital filtering. It is preferred to acquire both signals together and process them with a digital fourier analysis. This requires a significant processing apparatus for real time imaging. Alternatively, analog filtering to separate the frequency bands and dual channel data acquisition may also be used for real time implementation. The data acquired is processed by dual data pipeline data acquisition front ends, as described above. The resulting information is then combined by a data pipeline function that would process the low frequency information to find the blood/artery boundary and then switch to the high frequency attenuation and signal intensity for determining the material composition.

This technique effectively provides the output of both a low frequency sensor and a high frequency sensor at the same time. The low frequency information is useful for blood-to-artery separation and the high frequency information is useful for high resolution artery imaging. The lower frequency is preferably between 20 MHz and 30 MHz. This gives a good low blood scattering signal and good resolution of the artery edge. The upper frequency is preferably about twice the lower frequency, but this ratio may be from 1.5 to 3.

An alternative embodiment also incorporating two sensors in an imaging guide wire enables both side-looking and forward-looking imaging. In this alternative embodiment, one frequency sensor is pointed sideways and the other frequency sensor is pointed forward. This is readily incorporated in a 3 French imager, as described above, because the larger size device can possess an open end housing formed of a hypo tube in which the sensor is mounted. A forward-looking imager has the ability to provide information about where the imager is being pushed.

Multiple sensor devices may include more than two sensors and two frequencies. As long as the sensors do not overlap in frequency bandwidth significantly, more than two sensors could be used. This would be useful for 3D imaging where narrower bandwidth sensors are used and more of them are available for close, cross-sectional views.

3. <u>Guide Wire Tip</u>

Figure 13 shows an embodiment of the imaging guide wire in which the tip portion 452 incorporates features so that the imaging guide wire 450 can be used for both imaging and for positioning. In Figure 46, the tip section 452 of the imaging guide wire 450 includes a floppy tip 554 with a strain relief 556 section connecting the floppy tip 554 to the sensor section 454. The strain relief section 556 provides for a variable bending force between the floppy tip 554 and the relatively stiff sensor section 454. This can be provided by a gradually increasing core wire diameter or by gradually increasing the size or the diameter of the coil over the core wire.

In an imaging guide wire possessing positioning functions combined with imaging functions, one of the potential concerns relates to the inclusion of a long, floppy tip conventionally used with guide wires for steering in an artery. The concern is that the floppy tip may twist off or scuff up the inside of the artery during rotation of the wire during imaging. An embodiment feature that addresses this concern is illustrated in Figure 14. In this embodiment, a mechanism 558 is incorporated into the imaging guide wire 450 that allows the tip 452 to stay stationary with respect to the artery when the imaging guide wire is being rotated for imaging but locks the tip 452 to the wire when it is being used for steering during wire placement. This mechanism 558 includes a means for providing a fluid pressure on a hydraulic piston 560 in the guide wire. When the piston 560 is pressurized, the guide wire tip 452 is locked to the body of the imaging guide wire. When the pressure is balanced across the piston 560, the tip 452 will rotate freely.

4. Imaging Guide Wire Drive Cable

The drive cable section 456 is specifically adapted to address the mechanical and electrical requirements of the imaging guide wire. Mechanically, the drive cable 456 preferably possesses very good torque response in order to be used for intravascular positioning and good longitudinal stiffness for pushability. The drive cable 456 should also exhibit low angular whipping during rotation. Further, the drive cable section 456 should be very straight. Electrically, the drive cable 456 is preferably capable of sending a signal from one end to the other with minimum loss. In order to properly match the sensor impedance, high impedance in the drive cable 456 is preferred. The electrical impedance of the drive cable 456 is preferably in the range of 20 to 100 ohms.

An embodiment of the drive cable 456 is illustrated in Figure 15. The drive cable 456 includes a core wire 564, an insulation layer 566, a shield layer 568, and a coil layer 570. The core wire 564 may possess several alternative constructions. In one embodiment, the core wire 564 is formed of a solid wire. Alternatively, the core wire may be formed of multi-strand copper or silver-plated copper wires. The latter embodiment provides good electrical characteristics and allows the drive cable 456 to be relatively floppy. However, a multi-strand construction may not provide sufficient longitudinal stiffness. Therefore, the core wire may preferably be formed of a material having a high modulus of elasticity thereby increasing the longitudinal stiffness. Materials like stainless steel, tungsten, and beryllium copper are preferred. Of these, tungsten is most preferred since it has the highest yield strength and the highest conductivity.

To provide for low electrical loss in the core wire 564, a high conductivity material is applied to the outer surface of the core wire 563. Preferred materials for applying to the outer surface of the core wire 563 include silver or copper. Silver is most preferred since it has the highest conductivity. These materials are easily plated to a thickness suitable for good electrical transmission. At high frequencies, electrical current stays close to the surface of a conductor and therefore a 0.001 inch of conductor plating over the core wire is sufficient. In a preferred embodiment, taking into account both mechanical and electrical requirements, the ideal thickness of the coating is less than 0.001 inch.

The insulation layer 566 in the imaging guide wire separates the conductive core layer 564 from the conductive shield layer 568. For electrical purposes, this layer 566 is nonconductive and preferably has as low of an dielectric constant as possible. If a solid wire is used for the core wire 564, it is preferred that a means be incorporated into the insulative layer 566 to restrict longitudinal motion between the core wire 564 and the outer coil 568. If the insulative layer 564 is made of Teflon, a direct bond may be difficult to make between the layers. In this case, movement between the core wire 564 and the outer layers can be restricted at the joint between the drive cable 456 and the sensor housing 354. This is preferably accomplished by using a nonconductive sleeve to bond between the core 564 and outer layers that will be connected to the sensor housing 354. This sleeve is made out of glass ceramic or other hard, nonconducting material. To bond between the layers along the length of the drive cable, holes are formed in the Teflon at various patterns to allow glue or other bonding material to be used to connect the layers together.

A material other than Teflon can be used for the insulation layer 566. Such other materials include glass strands or a solid extrusion of glass, kynar strands, or a ceramic extrusion. The extrusions would form a solid, uniform layer over the core wire out to a given diameter. The strands would then be epoxied to form a composite layer much like a fiber glass or other composite structure that uses fiber and binder to generate a unique high strength material.

The shield layer 568 is located over the insulating layer 566 to make up the outer layer of a coaxial signal cable. The shield 568 can be made from a braid of wires or a coil of wires. In a preferred embodiment, these wires are rectangular silver-plated copper wires. A single layer of coils may be used to provide the smallest diameter drive cable. A low resistance shield layer provides for RF emission shielding and susceptibility. Cable loss is a function of the core and shield total resistance, and accordingly, it is desirable to provide the shield with as low resistance as possible. For this reason, it is preferred that a braid or double coil is used for the shield layer.

The outer coil layers 570 are needed for good torque transmission for performing the functions of both the drive cable and guide wire. The outer coil layers 570 are formed of copper or alternatively other metals like stainless steel. In a proximal section of the outer coil layer 570, a binder is used to bind all the layers together over a length thereof so as to make that portion of the imaging guide wire straight and stiff. This proximal section is from the proximal connector of the imaging guide wire to a location corresponding the end of the guide catheter with which the imaging guide wire would be used. This distance is typically 130 cm. This allows the distal section of the imaging guide wire to be relatively more flexible where it needs to go through tight bends.

Another alternative way to provide additional stiffness in a proximal section of the imaging guide wire drive cable 456 is to provide another layer of material over the metal coil outer layer 570 along a proximal section.

This additional layer may be formed of other-than-metal strands of glass, kevlar or other high strength materials. The strands would be used in a coil or braid layer over the core cable 570. The strands could then be epoxied to form a composite layer much like a fiber glass or other composite structure that uses fiber and binder thereby resulting in a unique, high-strength material. As described above, this can be a dual section composite in which one section is made out of one fiber and binder and the other section the same or different fiber and binder or a combination thereof.

5. Imaging Guide Wire Proximal Section

Referring again to Figure 34, a proximal section 458 of the imaging guide wire provides several functions. These functions include a connection for electrical contacts for signal transmission, torque transmission during imaging, torque and longitudinal motion during guide wire placement and a connection to an extension wire. Figures 16, 17, and 18 show alternative embodiments for the proximal section 458 of the imaging guide wire. In each of the three embodiments, the proximal section 458 has approximately the same diameter as the shaft portion 456 although the proximal section 458 could range in size from a little larger than the shaft portion 456 to much smaller. In each of these embodiments, the proximal section 458 provides for electrical connection. The electrical connection may be a static contact or a dynamic slip surface in which case there is a slip ring. Torque drive from the extension wire is accomplished by fitting over a smaller (round square or other shape) wire 571 as in Figure 16, or by fitting the wire inside a (round, square, or other shape) hole 572 as in Figures 17 and 18. The electrical contact connection 573 may be in an axially displaced configuration as shown in Figures 16 and 17. Alternatively, the contacts may be one inside the other as shown in Figure 18.

With these proximal contact configurations described above and shown in Figures 16 to 18, an extension wire 574 is plugged into the end of the imaging guide wire. The overall profile of the extension wire 574 and the imaging guide wire 450 maintains a small diameter as illustrated in Figure 19. The extension wire 574 is used for at least two purposes. First, the extension wire 574 allows an interventional catheter to be pushed into place over the imaging guide wire after the imaging guide wire has been positioned at the desired arterial location. Second, the extension wire 574 is used to clap on to for steering and pushing the imaging guide wire into place initially. Alternatively, a short tool could also be used that plugs into the end of the imaging guide wire that would allow steering and pushing the imaging guide wire to the desired location in the arteries.

When used for imaging, the proximal end of the imaging guide wire plugs into an interface drive device 576 that provides torque drive and an interface to transfer the electrical signals from the imaging guide wire electrical contacts. This connection is illustrated in Figure 20. This section 576 includes a proximal slip ring section 578 that would separate the rotating mechanical drive from the electrical signals on stationary hardware. This drive interface may incorporate any of the three slip ring alternatives, contacting, capacitive, and magnetic, as described above.

Embodiments of the proximal interface 576 are illustrated in Figures 21 and 21a. An external motion restrictor 580 is preferably used when rotating the imaging guide wire 450 to reduce any tendency for the wire to whip around in the radial direction. This restrictor 580 allows movement between the proximal assembly and the catheter through which the imaging guide wire extends. The restrictor 580 preferably allows for the placement of the catheter as well as movement of sensor within the catheter by pulling the imaging guide wire back and forward while maintaining the catheter stationary. Figures 21a and 21b illustrate two alternative embodiments for achieving this motion restriction. Figure 21a shows an embodiment in which a bellows type device 582 surrounds a portion of the proximal end of the drive cable 456. Figure 21b shows an embodiment in which a non-rotating close-fitting tube 584 is fitted inside the catheter. The use of a sterile contact plug 585 and a sterile sheath 586 allow for a convenient setup procedure, using inexpensive, disposable or easily sterilizable parts.

6. Imaging Guide Wire Ancillary Equipment

An imaging guide wire is a relatively fragile device and accordingly it is desirable to provide a means to maintain the wire's straightness. For example, during installation of any guide wire intravascularly, there are numerous possible occasions for the wire to be inadvertently bent and damaged. For this reason, an imaging guide wire holder and delivery device 590 may be used, as illustrated in Figure 22. For installing the imaging guide wire in a guide catheter 592 or any other catheter or sheath, the fittings 594 are connected between the catheter 592 and holder 590. An extension wire 574 (not shown) may be connected to the imaging guide wire 450 and then pushed to move the imaging guide wire 450 into place just before exiting the catheter 592. At this point, the fitting 594 is released and the extension wire 574 is pushed through the holder 590 while holding the imaging guide wire 450 steady. At this point, a clamp can be placed on the extension wire 574 to

push and steer the imaging guide wire into place. An interventional catheter may also be put in place at this time. The extension wire 574 is then removed and the proximal imaging assembly is snapped into place. Imaging would begin by rotating the wire 450 and moving it in and out.

B. Imaging Guide Wire Methods Of Use:

1. Method 1

In a first embodiment of operation, the imaging guide wire 450 can be used as the primary guide wire, i.e. to both position and to image. The imaging guide wire 450, described above, can be used in this manner. According to this method, the imaging guide wire is routed into place as a conventional guide wire. At this point, prediagnosis imaging may be performed if considered appropriate by the physician. Imaging may be done at this time by rotating the imaging guide wire in place. In this embodiment, the imaging guide wire possesses a nontraumatic tip and a smooth covering over the wire to reduce the possibility that the wire may damage the artery or the blood. In an alternative method of operation, a sheath may be routed over the imaging guide wire before the wire is rotated for imaging. This would also reduce or prevent any trauma in the artery at the location of the sheath. The tip of the imaging guide wire may extend distally outside this sheath or the imaging guide wire tip could be drawn back into the sheath before rotating. It should be noted that imaging can be performed in real time, and therefore to minimize problems with the rotation of a bare wire, the speed of wire rotation can be low, e.g. a fraction of a Hz or even done manually. If the imaging guide wire were rotated manually, a constant display can, at a minimum, provide information concerning distances.

Once the imaging guide wire is in place and an appropriate therapy is determined, a therapeutic catheter, e.g. a balloon dilation catheter, can be routed over the imaging guide wire to the desired arterial location. At this stage, the imaging guide wire can again be used to image by rotating the wire. Images obtained at this stage show the arterial cross section where the sensor is located. The imaging guide wire can then be moved and operated at the location where the treatment is performed. After the treatment, the imaging guide wire can be left in place while the catheter is removed and a second catheter is put in its place for yet another treatment if considered appropriate. Otherwise, the imaging guide wire can be moved to other locations to repeat the procedure, if necessary.

In a further alternative method of operation, once the catheter is in place over the imaging guide wire, the catheter and the imaging guide wire can be moved together to another arterial location. Here, the tip can extend distally outside the catheter and the image guide wire can be rotated and pushed to facilitate advancing and positioning the wire and catheter to the desired site. When used in this manner, the imaging guide wire can be used as a conventional guide wire. This has the potential to save time since the catheter would not have to be pulled back and replaced immediately for imaging and treatment.

2. Method 2

The above described method of operation is directed to the use of the imaging guide wire in conjunction with a conventional over-the-wire catheter in which the guide wire lumen extends the length of the catheter. Other types of catheter designs are available, such as the type of catheter in which the catheter has a short guide wire lumen (SGWL) at the distal end of the catheter and in which the guide wire occupies a location adjacent to the catheter proximal of a proximal entrance to the short guide wire lumen. If the imaging guide wire is used with a catheter of this type, somewhat different steps of operation may apply. With a short guide wire lumen catheter, the imaging guide wire may be first put in place in the artery. The imaging guide wire may be provided in a somewhat longer length, or a short extension wire can be connected to the device used in method 1. The short guide wire lumen catheter is then advanced over the imaging guide wire and pushed into the desired arterial location while holding the proximal end of the imaging guide wire. A concern is that the imaging guide wire is adjacent the short guide wire lumen catheter within the guide catheter over a considerable portion of its length. It may be desirable to reinforce the imaging guide wire shaft along this portion of its length so that it can be rotated without whipping. This may be done by applying a stiffening composite layer, for example. Alternatively, a reinforcing sheath may be positioned over the imaging guide wire up to the proximal guide wire lumen entrance. Such a reinforcing sheath is described in copending application Ser. No. 07/725,064 filed July 5, 1991, the entire disclosure of which is incorporated herein by reference. With these additional considerations accounted for, the imaging guide wire may be operated in a manner similar to those set forth above.

3. Method 3

According to this method, a conventional guide wire is first used with a conventional intravascular catheter. The guide wire and catheter are positioned in a conventional manner. The conventional guide wire is then withdrawn and the imaging guide wire is put in its place via the guide wire lumen of the conventional catheter. In this method, the imaging guide wire can be constructed somewhat differently from the imaging guide wire described above. If used with a separate, conventional guide wire for positioning, the imaging guide wire used in this embodiment need not possess a distal steering tip. Instead, all that would be required would be a smooth end sensor section. A non-traumatic short soft tip may be included at the end of the sensor section for extending beyond the end of the catheter into the artery. Further, in this embodiment the proximal end of the imaging guide wire does not have to pass through the catheter, and accordingly, there is no size restriction on how large it is. A proximal connection could be used very similar to what is described for use with the 3 Fr imaging device, described above.

4. Method 4

In this method, a conventional guide wire is used with a dual lumen catheter. A dual lumen catheter is disclosed in copending applications Ser. Nos. 07/704,828, filed May 23, 1991 and 07/809,715 filed December 18, 1991 the entire disclosures of which are hereby incorporated by reference. According to this method, a conventional guide wire is advanced into the desired arterial location. The dual lumen catheter is routed over the conventional guide wire using one of the lumens. This lumen can be the full length of the dual lumen catheter or can be merged into the first lumen at any point proximal from the distal tip. For the dual lumen catheter, the conventional guide wire is then partially pulled back to allow the imaging guide wire to image through that section and extend beyond the end of the dual lumen catheter. In this method, any of the imaging guide wire embodiments may be used. If an imaging guide wire, as described above in method 1 is used, the imaging guide wire could be left in place and the catheter could be moved or exchanged over it.

C. CCD Data Capture and Sensor Configurations

Among the major obstacles associated with ultrasonic imaging configurations are the matching of impedances between the sensor and the signal cable, transmitting the signal down the cable with minimal loss, and maintaining a high signal to noise ratio. For phased array sensors, described below, and two dimensional sensor arrays, there are additional problems related to parallel signals, such as crosstalk and multiplexing limits.

In a further embodiment of the present invention, an imaging transducer sensor is provided having a charge coupled device, (CCD), associated therewith. The CCD is an integrated circuit that could be used to capture the high frequency waveform of the sensor and send it back to the proximal end of the device preferably both amplified and at a lower frequency. The charge coupled device (CCD), as referred to herein, may be one of a family of charge transfer devices which may also include charge injection devices.

Referring to Figure 28, there is depicted a distal end of a imaging device 360 including a CCD 362, a PZT transducer 364, a matching layer 366, a backing material 368 all mounted in a holder 370. The signal from the transducer 368 is input to the CCD 362. The electrical connections 372 between the CCD 362 and the signal and power wires 374 would be made using standard IC wire bonding techniques. The input impedance of the cell can vary widely based on the cell capacitance and input resistance. This input impedance would be designed to give the best pulse ringdown. The pulse is generated by the CCD IC or alternatively the pulse may come from a proximal pulser, as in the embodiment described above. After the pulse, the CCD would be clocked to store the input waveform from the sensor 364. After the waveform is acquired, further clocking of the CCD array at a slower frequency will allow the "reading" of the stored value and transmitting this to the proximal electronics for further processing and display.

The device 360 provides numerous advantages for intravascular ultrasound imaging. It allows nearly perfect impedance matching independent of the sensor. It allows the reduction in frequency of the transmission of the signal to the proximal end at very low noise susceptibility or emission. This would allow the reduction of the current coaxial wire design to a single wire signal design. As few as two wires would be necessary if the pulsing is remote and communications are done over the power lines.

In the embodiment shown in Figure 28, the CCD 362 and the sensor 364 are next to each other. By using a PZT sensor with PVDF matching layer with an overhang tab for top contact connection, the connection between the sensor and the CCD is made by having a large metal pad on the IC to contact the PVDF conductive layer.

In an alternative embodiment 375 shown in Figure 29, a transducer 376 located over a CCD 378. This embodiment uses a copolymer material for the transducer 378 and mounts it over the CCD 378. This provides an electrical sensor plane as part of the CCD 378 by using a large area top conductive layer.

In further related embodiments, a CCD array can be used in sensor devices having more than one sensing area, e.g. phased arrays and linear arrays such as described in the specification below, for sequential sensors mounted along the axis of the device for 3-D imaging. Such embodiments utilize the same type of circuit for the CCD array as described above but use parallel paths. Such a configuration is similar to that currently being used in cameras. The CCD imaging catheter functions as follows. Photons excite the electrons that are stored into a 2-D CCD shift array. Once the values are loaded into the shift array, they are then shifted to one edge of the IC one row at a time where they are shifted in the other dimension to a circuit that measures, amplifies and sends out the information one pixel at a time. A device very similar to this could be used in phase arrays, where like the single sensor CCD, the signal is read and input into the CCD at one end of the shift register and it comes out the other end. This would allow the simultaneous acquisition of all of the sensor array elements and allow the transfer of the total information to the proximal circuitry with very little loss or distortion from noise or crosstalk. Here, as in the single sensor design, the sensor material could be located over the CCD or next to it.

This concept could be extended further in an embodiment of a CCD acoustical sound beam imager. This device would be similar to that of CCD arrays used in cameras, however, instead of having a cell area designed to generate electrons from a light source, the charge could come from a small area of piezoelectric material. The piezoelectric material could be placed over the CCD surface areas would be defined on the top metallization layer of the IC that would capture and transfer the piezoelectric charge into the input cell of the 2-D shift register array. Once the data are loaded into the shift array, they are then shifted to one edge of the IC one row at a time where they are shifted in the other dimension to a circuit that measures, amplifies and sends the information out one pixel at a time. This device would be able to take a snapshot of all the acoustical 2-D wave front one point in time.

This concept could be even further extended to provide for a shift register for each of the acoustical pixels. This would allow for capturing all of the 2-D waveforms in time. Such a device would be very useful for 3-D imaging in a non-moving device. A forward-looking configuration could be constructed in which the device is placed at the end of the catheter or is placed behind an acoustical lens in the focal plane. This would allow the acquisition and direct display of the image within the focal region of the device. Acoustical excitation could be generated by a single pulse from a dispersive acoustical generator. This generator could be a piezoelectric layer over the CCD.

D. Sequential Sensor Mounting for 3-D

Three dimensional (3-D) images would be very useful to visualize the extent of certain diseases present in vessels. 3-D imaging allows for slicing, rotating and displaying the information so that volume and cross sections can be visualized. A 3-D reconstruction requires information from a number of 2-D cross sections as well as information about their corresponding position along with the vessel. Acquiring information for 3-D reconstruction can be obtained by starting at one position in the artery and moving the sensor past the area to be reconstructed. There are drawbacks associated this technique, however, such as the fact that in coronary arteries the rotational axis of the artery is hard to define in time since this axis is moving. Also, obtaining good distance measurements along the length of the artery can be difficult because of the stretching of the drive shaft or the sheath especially if the whole catheter has to be moved. This stretching can present a problem since the displacement distance may be measured proximally with a distance transducer. For example, as the catheter or the drive shaft is pushed in from a proximal end, friction could prevent the sensor from moving at all. This would produce a significant distortion in the 3-D reconstruction. Also, the duration of time needed to acquire all the information required for a 3-D reconstruction could be a drawback by limiting the capability for rapid update of the 3-D image.

Referring to Figure 30, there is depicted a distal end of an ultrasonic imaging device 390 that provides for 3-D imaging. This device contains multiple sensors 392 along its axis. The multiple sensors 392 are located and mounted in a mounting holder 394 which is mounted on a distal end of a drive cable 396. The holder 394 would be connected to the drive cable 396, and driven thereby, in a manner similar to that used for mounting a single sensor holder. The multiple sensors 392 may include an arbitrary number of sensors depending on the number of cross sections required. Each sensor would be located at a constant, known spacing in the mounting holder 394. The sensor holder 394 may have flexible sections 398 between each of the sensors so that each of the sections can flex as it is being rotated. This could also facilitate delivery and use of this device. Each of the multiple sensors 392 would be operated to scan the cross section where it is positioned.

There are alternative transmission schemes for transmitting the information signals from each sensor section to the proximal end of the device. For example, the signals from all the sensor sections could be transmitted in parallel, or alternatively, signals from each individual sensor section could be transmitted one at a time by multiplexing, or a combination of these two methods could be used. A multiplexer would select which sensor section is currently active and send its signal down the cable. There may be some advantages in transmitting one signal at a time using a multiplexer at the proximal end of the sensor array, such as a reduction in crosstalk between channels and the elimination of multiple high frequency signal wires.

The conditioning hardware for reconstructing a 3-D image in a reasonable amount of time may include parallel processing units each working on a section of the image. Each one of these could require a powerful processor. Economies may be provided by using a network of Intel I860 type processors. The data acquisition and data pipelining would be very similar to that described elsewhere in this specification. The 3-D processing might be best implemented in the raw data pipeline. Alternatively, it could be implemented as a parallel data path into a graphics pipeline allowing simultaneous display of one of the sensor's cross section being displayed in real time along with a 3-D image of the total region.

In a further embodiment, these multiple sensors could be used in a phased sensor operation in which the beam is swept and pointed along the axis of the device. This may be a desirable configuration since it would allow some "forward-looking" along with 3-D acquisition. If this were implemented, it would be preferable that the sensor elements be constructed having a smaller dimension in the direction along the device axis.

For a sensor array configuration, the sensor sections would not have to be rotated to obtain an image. By holding the device motionless, an image would be obtained of a cross section of the wall of the artery facing the sensors. This would for most applications be very useful information. 3-D information could still be obtained by rotating the whole device.

E. Acoustical indexing for 3-D

An alternative approach to 3-D imaging is shown in Figures 31 and 32. This alternative approach would use a longitudinal indexing pattern 400 on a sheath 402 for 3-D imaging. The indexing pattern could be made to vary along the length of the sheath 402. The pattern 400 would be used to determine the location along the length of the sheath 402 at which the transducer (which would be insider the sheath as in the previously described embodiments) is located. This information could be used for acquiring 3-D information of the artery as the transducer was moved with respect to the sheath. The pattern 400 could possess a binary pattern, a gray scale pattern, or other patterns to indicate a change in position between the sheath and the transducer. The pattern could be applied over just the distal length on the sheath or over the entire length.

The pattern 400 may be encoded for incremental or absolute registration. For incremental registration, only one bit of information would be required. In such a case, external direction information would typically be generated. For absolute registration, two bits of information would be provided and used in quadrature, thereby allowing the direction to be determined. For absolute position information, gray scale encoding may be preferable. Gray scale coding has the property that only one bit changes in going from one state to the next. This prevents errors compared to binary scale for example, since there is no way of ensuring in binary scaling that all bits will change simultaneously at the boundary between two encoded values for binary or other codes.

Patterns for both radial acoustic indexing and 3-D lateral indexing may coexist on the sheath. Both patterns could be formed of the sheath material or could be formed of different materials. One pattern could be formed on the inner side of the sheath while the other on the outer side. Also, these patterns could be formed on the same surface.

Data Graphics Pipeline Architecture

In ultrasonic intravascular imaging, a large amount of data needs to be processed between the transducer being pulsed and the image being displayed and various means can be used for this processing. For example, processing can range from all analog to all digital. In most digital systems, the conditioned signal is acquired through data acquisition, processed by a computer, and displayed through some graphics hardware. This can be accomplished over a computer buss as long as there is a limited amount of transferring being done. Current systems are very basic in the digital conditioning and image processing, and can utilize this approach.

It would be preferred to use digital conditioning functions to enhance the ultrasonic image or to provide for feature extraction. This would likely require a different data flow architecture to provide for additional data transfers needed to produce the image reasonably quickly. Figure 33 depicts a pipeline structure that provides this architecture. This architecture includes a dual pipeline: one for raw data and another for graphics data. The analog input from the sensor/conditioning is acquired from a high speed data acquisition circuit. This circuit

synchronizes the raw data pipeline and transfers the data down the pipeline at a lower speed. The data is passed from one function to the next in real time or near real time speeds. This pipeline basically processes polar data. Since there would be much less data in the polar domain, it would be preferable to process this data as much as possible. These processing functions may include deconvolutions, fourier transform processing, neurocomputing processing or other techniques to enhance the raw data and do feature extraction.

Some of these pipeline functions include the provision for recording and playback of raw data. Also, a function may be provided for the buffering of raw data as the catheter is advanced or withdrawn through the guide wire lumen of the interventional catheter. This would provide the physician with information about the entire artery from the incision location to the coronaries. This data would likely not need to be viewed at the time it is obtained, however, it would be available for analysis off line after the procedure. The raw data can be stored on an optical disk, e.g. a WORM, that can store up to 1 Gbyte of data. It is estimated that during the relatively short period of time that the imaging guide wire is being advanced or withdrawn through the guide wire lumen of the catheter, the data is being generated at a rate of approximately 100 Mbytes/minute.

A small variation on this architecture would include the addition of parallel pipelines. This could be done for example by taking the raw data acquisition output, branching off to a second LUT, and combining the two at the initial graphics pipeline function. This would allow two displays of the same raw data at the same time in different locations on the screen. This would be desirable if a real time enhanced display is desired while at the same time showing a slower 3-D reconstruction or enhanced feature detection.

The data pipeline and graphics pipeline architecture, as described above, are advantageously integrated into a system environment. Figure 23 shows the pipeline structure integrated into one type of system environment. Figure 23 shows how the communication portion of the architecture can be implemented to allow the central system CPU to handle pipeline setup and configuration. This allows user input to effect changes in overlays, images and signal conditioning of data. Not every pipeline function may require a direct interface to a common buss. An alternative to common bussing is daisy-chained communications. Here, the common processor would be able to perform the setup and configuration tasks using a serial or parallel communication link. An external controller may be provided in the overall system configuration. This controller may issue commands to the system or may be directly memory-mapped to the functions on the system. This intersystem communication may employ techniques known and accepted to those of skill in the art. In the first method, the external controller may be connected in a serial or parallel manner and communicate with the system CPU. As with the keyboard, these commands can be queued and processed, or a handshaking can occur for synchronized command execution and communication. The memory-mapped external system control is performed by having the external system take control of the system common buss and accessing the hardware and memory directly.

Non-contacting slip rings

With mechanical rotating imaging transducers, one of the major concerns relates to making a good electrical contact between the rotating drive shaft and the proximal electronics from the proximal end of the imaging device. In a previous embodiment in a 3 Fr size imager, the transmission of the electrical signal from the imager elongate shaft to the proximal electronics is provided by a mechanical contacting slip ring assembly. Although the slip ring assembly, as described above, provides excellent transmission, in alternative embodiments, it would be advantageous, and potentially a simplification of the interface, if a non-contacting means were employed to couple electrical signal between the rotating and non-rotating parts. Two alternative means for providing this transmission link are capacitive coupling and magnetic coupling.

A first embodiment of the signal coupling assembly is shown in Figure 24. This embodiment employs capacitive coupling. Capacitive coupling can be used when the capacitance is large enough between the rotating and non-rotating contact rings. The capacitance is a function of the surface area, the gap distance and the effective dielectric constant. For a 30 Mhz signal, 100 pF would be more than enough capacitance to provide suitable coupling. A values greater or less than this would work also.

Capacitive contact rings 600 are shown to be longitudinally spaced, although alternatively, the rings 600 could be positioned radially. If positioned radially, one ring would be placed on the inner diameter and the other contact ring on the outer diameter of the assembly.

With either capacitive or magnetic non-contacting slip rings, the mechanical energy is transferred by a keyed configuration or a friction fit. There are other means that could be used to transfer the mechanical energy, for example by a magnetic drive. By making the rotating contact rings out of a magnetic material or by placing a permanent magnetic in the assembly, the slip and drive shaft could be rotated without physical contact. A similar principle is used in stepper motors. There are several well known ways of generating an appropriate rotating magnetic field that the rotating contact rings would follow or of generating a stepping multi-phase magnetic field that would drive the center through the rotation phases that following the stepper rotation.

Figure 25 shows an embodiment of a magnetic non-contacting slip ring assembly 604. This alternative embodiment includes a rotating and a non-rotating transformer coil 608 and 610. The energy is transferred by magnetic fields through the magnetic circuit. A consideration with this embodiment is air gaps reducing the coupling between the two coils. For this reason, the gap area 612 is enlarged to minimize this problem.

K. EEPROM Catheter Information Storage

In present preferred arid alternative embodiments of ultrasound imaging catheters, there are numerous parameters that are device dependant. Currently, all imaging device dependant information is entered manually or by shunting contact pins to provide some device type information. These parameters may be as simple as device type, frequency, device serial number, and production information. Other imaging parameters that are sensor dependant include those that would be used for a calibrated waveform pulser or coefficients that describe the acoustic waveform that would be used in image enhancement routines, as described above. This information must be entered into the system before imaging begins. However, it is not very user-friendly to force the user to enter the information manually into the system.

A feature that can be incorporated into any of the embodiments discussed herein provides for automatic imager information entry. An embodiment incorporating this feature is shown in Figure 26. The device dependant information is stored in a non-volatile storage medium 614. Such a storage medium is an EEPROM. In this embodiment, the information is available when the imaging catheter or imaging guide wire is plugged into the driving apparatus and control system. The means for connection could be direct wiring or an isolated reading means could be used. A minimum of two wires are typically needed to transfer information. Common serial EEPROM devices are available that operate off three wires and have a wide range of storage capacity. Also potentially available but not as desirable is parallel access non-volatile storage.

Another easy method of entering this information is to provide a separate data card or disk. This can be plugged into the system and the computer control can read the information before imaging begins.

L. Cath Lab System Integration

To use the imaging catheter or guide wire, drive and electrical connections must be made. A setup for achieving and facilitating this type of activity is illustrated in Figure 27. Figure 27 shows a motor box 620 attached to the edge of a patient table 622. A gooseneck device 624 extends the catheter connector over the table 622 and holds the imaging catheter or guide wire in place. It is important to keep the imaging catheter or guide wire straight while imaging. This gooseneck type device 624 allows movement back and forward easily to follow to doctor as the imaging is performed. Before and after imaging, the gooseneck device 624 and imaging catheter can be pushed back out of the way to eliminate some of the clutter on the patient table 622 as well as to protect the imaging drive shaft from getting bent. This gooseneck device 624 could have cables internal or external to its supporting structure. The goose neck device 624 preferably possesses a physical configuration and structure that can support a weight at a distance and be moved between two three-dimensional points.

Ultrasound imaging in catheter labs is currently performed by wheeling an ultrasound imaging system into the cath lab, setting up the system and catheter and then imaging. There are other methods of system integration that depend on the catheter lab setup. In prior cath lab setups, a direct connection is made between the motor 630 and conditioning unit (MCU) 632. The motor is typically in a cabinet on a cart and the MCU is mounted on the table. In this configuration, the proximal drive cable is laying across the floor and can be tripped on if the system is not next to the doctor. When the system is not next to the doctor, the MCU should have a connector on the floor, the table or hanging from the ceiling.

According to a preferred setup, a connector 634 is mounted to the table 622 so the MCU 632 cable follows the table 622 when it is moved. The system also has a plug 636 and could be unplugged for portable configurations. In this configuration, there is also a connector for video input from the fluoroscope and video outputs for displaying on the doctors' overhead monitor.

Other system configurations include a rack mount system integrated into existing or modified catheter lab control hardware. In this configuration, the system is already on-line and when the doctor needs to perform an imaging procedure, the MCU 620 is mounted to the table 622 and plugged in. At this time, imaging could begin. The external controller could issue the system commands and the video outputs are multiplexed and displayed at the doctors overhead screen.

Another alternative configuration provides for the system to be located within the MCU 620. This could be provided if the system electronics were small enough to fit within a reasonable sized box to place on the table rack. Here, there is a manual interface on the unit and that can be operated remotely from an external controller. Also, a small monitor can be provided internally, but the preferred method of viewing would be ex-

ternally on the overhead monitor. In this configuration, there is a plug for communications, video signals and power.

It is intended that the foregoing detailed description be regarded as illustrative rather than limiting and that it is understood-that the following claims including all equivalents are intended to define the scope of the invention.

Claims

1. An imaging guide wire for navigating into small vessels of a person's vasculature and imaging the small vessels from within, comprising:

   an elongate drive shaft having dimensions suitable for positioning into small vessels of the person's vasculature via a lumen of a conventional catheter, said elongate shaft having a size to be positioned in and advanced via a guide wire lumen of the conventional catheter into the small vessels of the person's vasculature;

   a transducer portion connected to the distal portion of the elongate shaft, said transducer portion also sized to be positioned into the small vessels of the person's vasculature via the lumen of the catheter;

   a proximal section connected to the proximal end of the elongate shaft for transmission of electrical signals from a proximal control apparatus to the transducer via the elongate drive shaft and also to transmit mechanical energy from a proximal drive apparatus to the elongate drive shaft to rotate the transducer for imaging.

2. An imaging guide wire as claimed in Claim 1 in which said elongate drive shaft is not more than approximately 0.018 inch.

3. An imaging guide wire as claimed in Claim 1 or Claim 2 in which said transducer portion is mounted in a transducer housing mount having an aperture therein through which ultrasonic signals can pass, said aperture having a dimension of approximately 0.012 inch.

4. An imaging guide wire as claimed in any one of the preceding claims in which said transducer portion is comprised of:

   a piezoelectric sensor having a face portion, said face portion comprised of a plurality of separate elements.

5. An imaging guide wire as claimed in Claim 4 in which said separate elements are formed of a single piezoelectric material having slices formed in the face thereof.

6. An imaging guide wire as claimed in Claim 5 in which said slices are parallel to a longitudinal axis of the drive shaft.

7. An imaging guide wire as claimed in Claim 5 or Claim 6 in which two or more of said plurality of elements are connected to a single pair of cable leads for simultaneous excitation of said two or more elements.

8. An imaging guide wire as claimed in Claim 7 in which all the elements forming said transducer portion are connected to a single pair of cable leads for simultaneous excitation of all the elements.

9. An imaging guide wire as claimed in any one of Claims 5 to 8 in which said elements are connected across the thickness of the elements.

10. An imaging guide wire as claimed in any one of Claims 5 to 8 in which said elements are connected across the width of the elements.

11. An imaging guide wire as claimed in any one of Claim 5 to 10 in which said transducer portion is mounted in a transducer housing mount having an aperture therein through which ultrasonic signals can pass, and in which said aperture is circular and in which the slices are formed as straight lines parallel to a longitudinal axis of the drive shaft.

12. An imaging guide wire as claimed in any one of Claims 5 to 10 in which said transducer portion is mounted in a transducer housing mount having an aperture therein through which ultrasonic signals can pass, and

in which said aperture is circular and in which the slices are formed as circular concentric slices forming circular elements.

13. An imaging guide wire as claimed in any one of Claims 5 to 10 in which said transducer portion is mounted in a transducer housing mount having an aperture therein through which ultrasonic signals can pass, and in which said aperture is circular and in which the slices are formed as spiral slices forming spiral elements.

14. An imaging guide wire as claimed in any one of Claims 3 to 13 in which surfaces of the sensor and the mount are treated to increase the surface tension between the surrounding fluid and said surfaces.

15. An imaging guide wire as claimed in any one of Claims 3 to 14 further comprising:
a protective sheath formed over the aperture over the transducer portion.

16. An imaging guide wire as claimed in Claim 15 in which said sheath is formed in a shape having a surface that fills the space in front of said transducer portion.

17. An imaging guide wire as claimed in any one of Claims 3 to 16 further comprising:
an exponential matching layer located over the aperture over said transducer portion, said exponential matching layer being formed of a series of layers in which the impedance follows in an exponential manner from one layer to another.

18. An imaging guide wire as claimed in any one of the preceding claims further comprising:
a backing layer located on a back side of said transducer portion;
and a spline structure mounted adjacent the backing layer.

19. An imaging guide wire as claimed in any one of the preceding claims in which said transducer portion is a wedge geometry transducer.

20. An imaging guide wire as claimed in Claim 19 in which one of the backing surfaces of said wedge geometry transducer has a quarter wavelength grating surface located thereon to attenuate reflections from said surface.

21. An imaging guide wire as claimed in any one of the preceding claims further comprising:
a control apparatus connected to the proximal section for sending and receiving signals, said control apparatus further comprising:
a vector averaging circuit to filter out fast moving blood scattering return signals.

22. An imaging guide wire as claimed in any one of the preceding claims in which said transducer portion is comprised of:
a first sensor for operating at a first frequency; and
a second sensor located over said first sensor, said second sensor for operating at another frequency.

23. An imaging guide wire as claimed in any one of the preceding claims further comprising:
a floppy spring tip connected to and extending distally of said transducer portion, whereby the imaging guide wire can be used for positioning an intravascular catheter as well as for imaging arterial features accessible by means of the guide wire lumen of the intravascular catheter.

24. An imaging guide wire as claimed in Claim 23 further comprising:
a strain relief section connecting the floppy tip to the transducer section.

25. An imaging guide wire as claimed in Claim 24 in which said strain relief section comprises a gradually increasing core wire diameter.

26. An imaging guide wire as claimed in any one of Claims 23 to 25 further comprising:
a releasable locking means connected to said tip to allow said tip to stay stationary with respect to the artery when said transducer portion is being rotated for imaging and which locks said tip to the transducer portion when said imaging guide wire is used for steering.

27. An imaging guide wire as claimed in Claim 26 in which said releasable locking means comprises:

a means for providing a fluid pressure on a hydraulic piston, said piston connected to said tip, whereby when said piston is pressurized said tip is locked to the transducer portion.

28. An imaging guide wire as claimed in any one of the preceding claims in which said drive cable comprises:
a core wire;
an insulation layer surrounding said core wire;
a shield layer surrounding said insulation layer;
and
a coil layer surrounding said shield layer.

29. An imaging guide wire as claimed in Claim 28 in which said core wire comprises:
multi-strand, plated copper wires.

30. An imaging guide wire as claimed in Claim 29 in which said core wire is plated with a high conductivity material to a thickness of less than 0.001 inch.

31. An imaging guide wire as claimed in Claim 29 or Claim 30 in which said core wire is plated with silver.

32. An imaging guide wire as claimed in Claim 28 in which said core wire comprises:
a solid wire of a material having a high modulus of elasticity to increase longitudinal stiffness.

33. An imaging guide wire as claimed in Claim 32 in which said core wire is comprised of a material selected from stainless steel, tungsten, and beryllium copper.

34. An imaging guide wire as claimed in Claim 32 or Claim 33 in which said insulation layer is formed of a material selected from Teflon, glass strands, a solid extrusion of glass, kynar strands, and a ceramic extrusion.

35. An imaging guide wire as claimed in any one of Claims 28 to 34 in which said insulation layer comprises:
a means to restrict longitudinal motion between said core wire and said shield layer.

36. An imaging guide wire as claimed in any one of Claims 28 to 35 in which said shield layer is formed of a braid of rectangular silver-plated copper wires.

37. An imaging guide wire as claimed in any one of Claims 28 to 36 in which said outer coil layers are formed of a material selected from copper and stainless steel.

38. A data processing architecture for use in an imaging device for ultrasonic imaging of small vessels of a patient's body, the imaging device having a transducer sized and adapted to be positioned intravascularly to scan small vessels of the patient's body from within a small vessel, a drive cable having a distal end connected to the transducer and operable to transmit electrical signals to and from the transducer and to rotate the transducer to scan the vessel of the person's body with ultrasonic waves, and a signal processor adapted for generating and receiving signals to and from the transducer via the drive cable, the data processing architecture comprising:
a raw data pipeline adapted to process polar coordinate data derived from the signals produced by the transducer;
a means connected to said pipeline for storing raw data produced during advancement of the imaging device to the small vessels or withdrawal of the imaging device from the small vessels;
a means responsive to the raw data pipeline and a look up table for converting data from the raw data pipeline to rectangular coordinate data and outputting rectangular coordinate data; and
a graphics data pipeline responsive to the output of the converting means.

39. In an imaging device for ultrasonic imaging of small vessels of a patient's body, the imaging device having a transducer sized and adapted to be positioned intravascularly to scan small vessels of the patient's body from within the small vessel, a drive cable having a distal end connected to the transducer and operable to transmit electrical signals to and from the transducer and to rotate the transducer to scan the vessel of the person's body with ultrasonic waves, a signal processor adapted for generating and receiving signals to and from the transducer via the drive cable, and a motor adapted for connecting to the drive cable to rotate the transducer, a coupling member to connect a proximal drive cable to the signal processor and the motor, the coupling member comprising:

a mechanical connector for releasably connecting the motor to a proximal end of the drive cable;
a non-contacting signal transmission apparatus having;
a rotating portion adapted to releasably connect to the proximal end of the drive cable; and
a non-rotating portion connected to the signal processor and to transmit signals between said signal processor and the rotating portion, said rotating and said non-rotating portions not being in contact with each other along the signal transmission path.

40. A coupling member as claimed in Claim 39 in which said rotating and non-rotating portions further comprise:
capacitive sensing means to transmit and sense the signal between said rotating and non-rotating portions.

41. The coupling member as claimed in Claim 39 in which said rotating and non-rotating portions further comprise:
magnetic means to transmit and sense the signal between said rotating and non-rotating portions.

42. An imaging device for ultrasonic imaging of small vessels of a patient's body, the imaging device connectable to a signal processor for generating and receiving signals to scan the vessels with ultrasonic pulses from within, the imaging device comprising:
a transducer sized to be positioned into the small vessels of the person's vasculature to scan the person's vasculature with ultrasonic pulses from within;
an elongate drive shaft connected at a distal portion thereof to the transducer, said elongate drive shaft also having dimensions suitable for positioning into small vessels of the person's vasculature, said elongate drive shaft adapted to transmit electrical signals there through between the signal processor and the transducer; and
an information storage medium associated with the imaging device, said information storage medium adapted to store device specific information about the imaging device and be readable by the signal processor when the device is connected thereto.

43. An imaging device as claimed in Claim 42 in which said information storage medium is located in a portion connected to the drive shaft.

44. An imaging device as claimed in Claim 43 in which said information storage medium is an EEPROM.

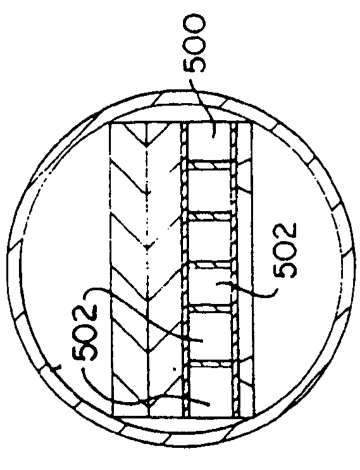


FIG. 2A

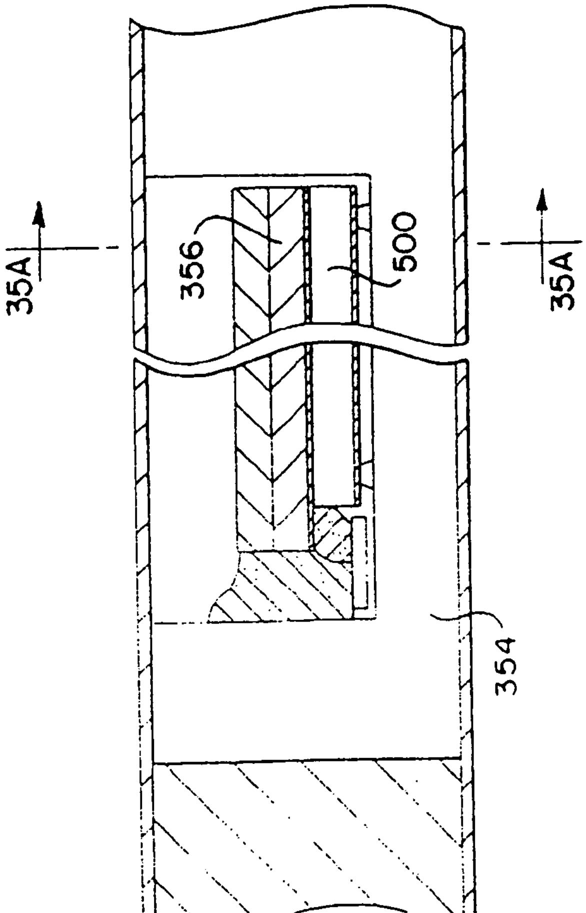


FIG. 2

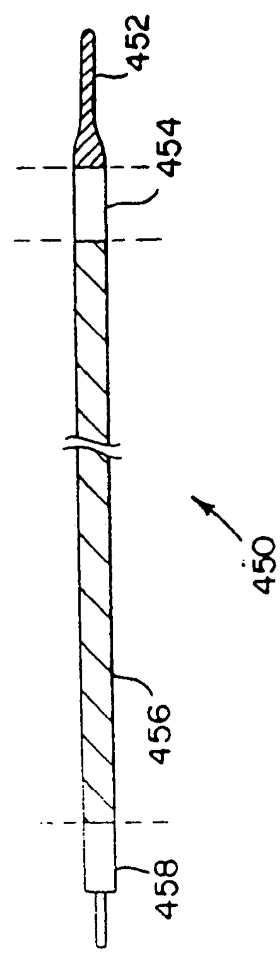


FIG. 1

FIG. 3

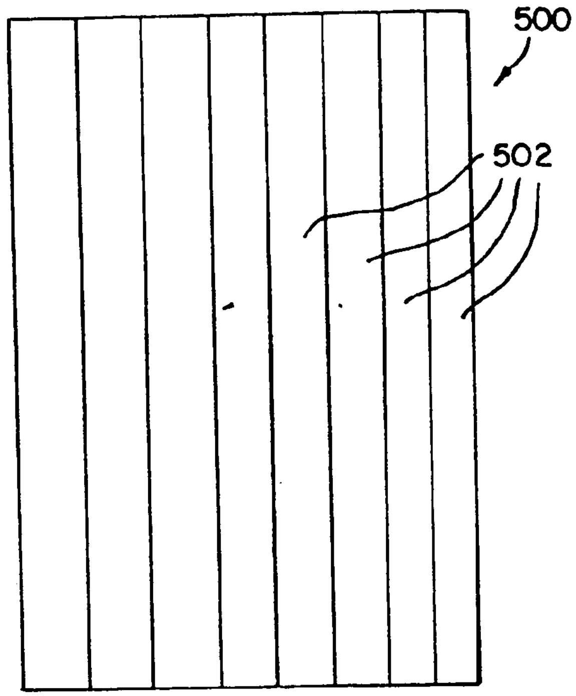


FIG. 4

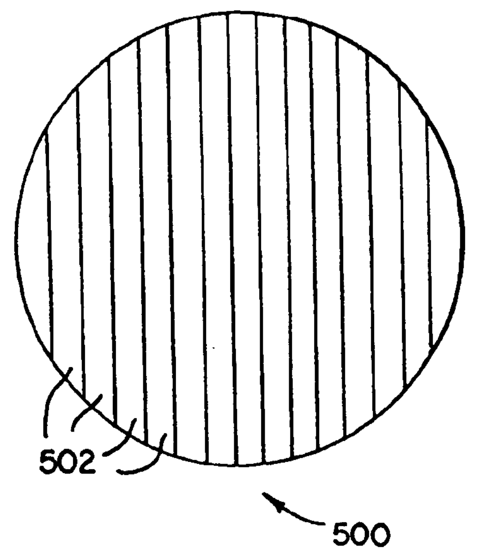


FIG. 5

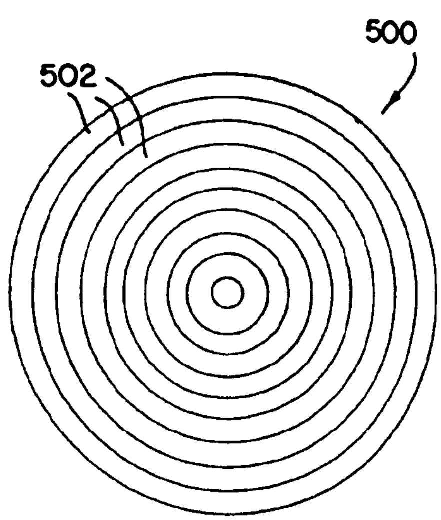


FIG. 6

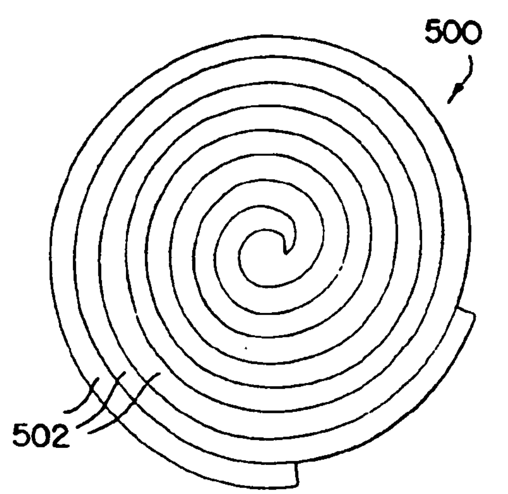


FIG. 7A

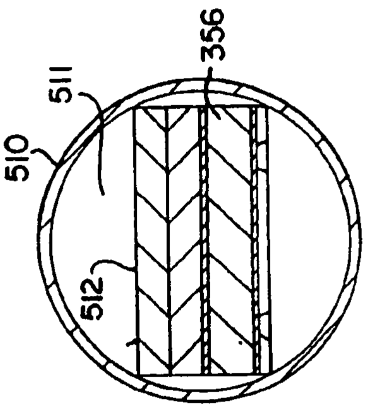


FIG. 8A

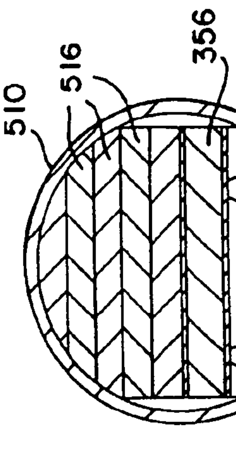


FIG. 7

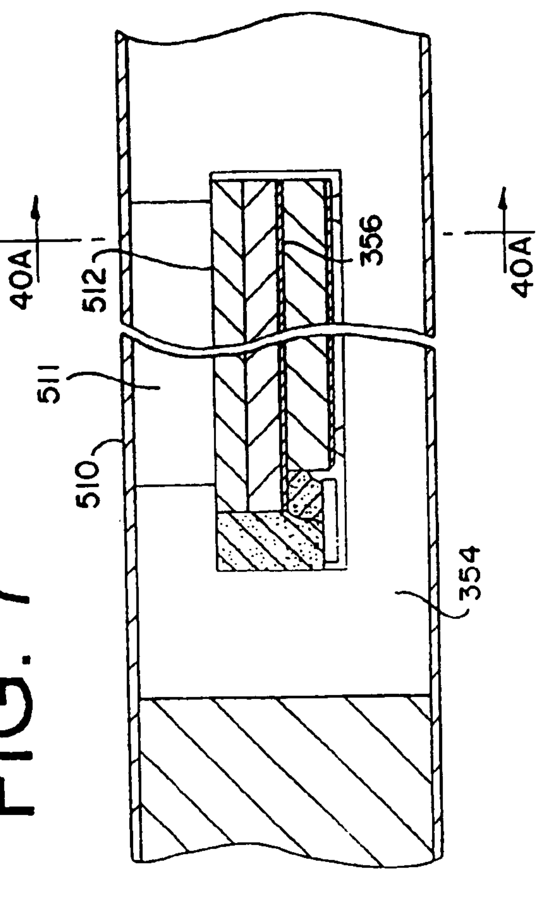
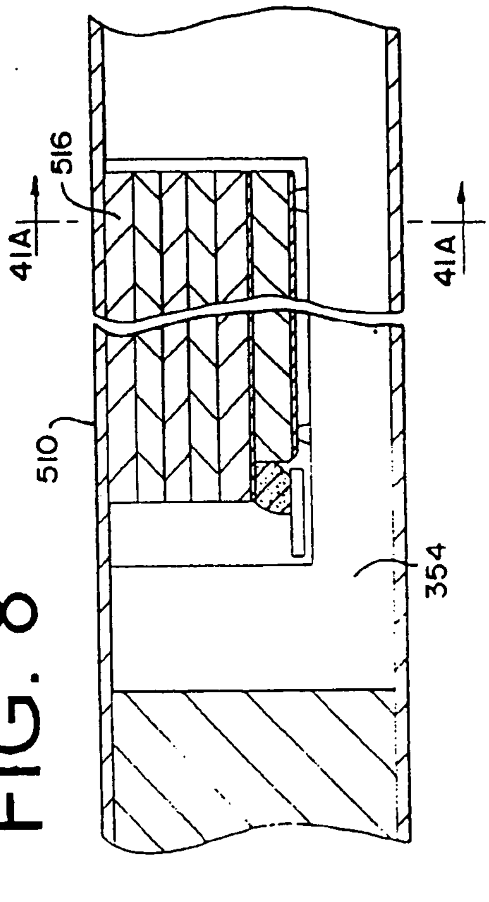


FIG. 8



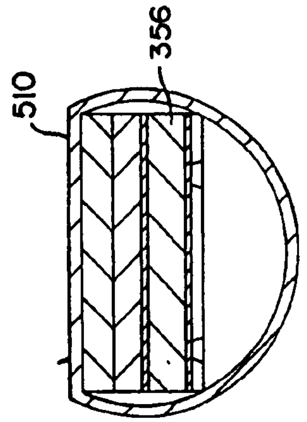


FIG. 9A

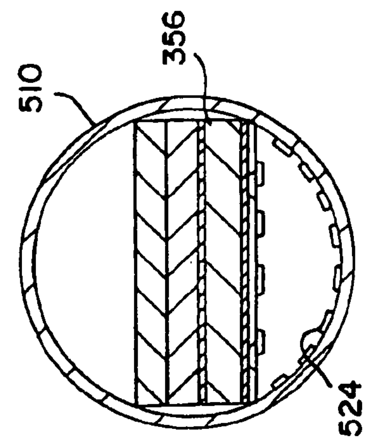


FIG. 10A

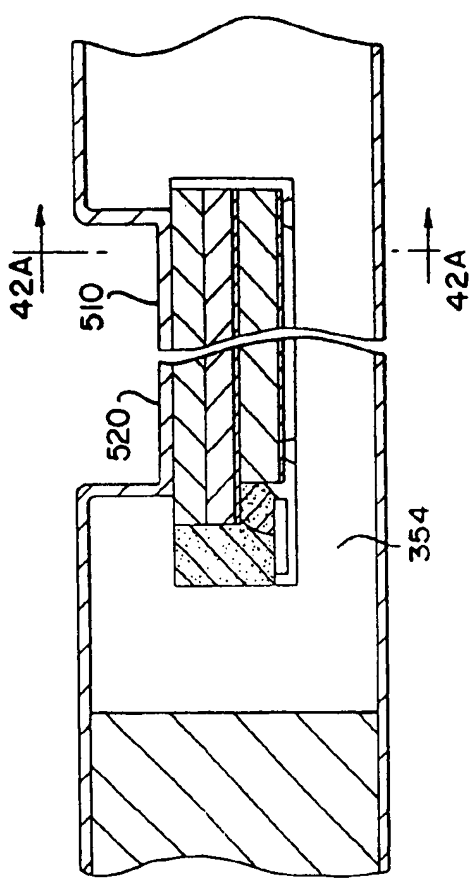


FIG. 9

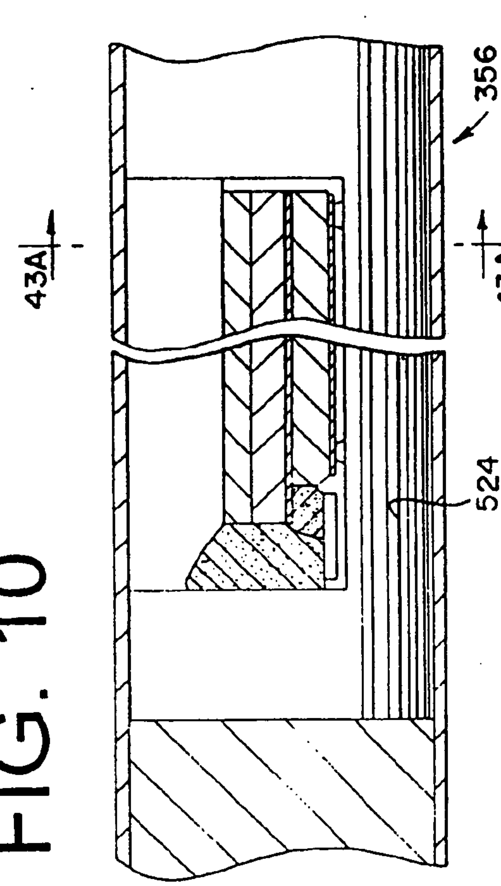


FIG. 10

FIG. 11A

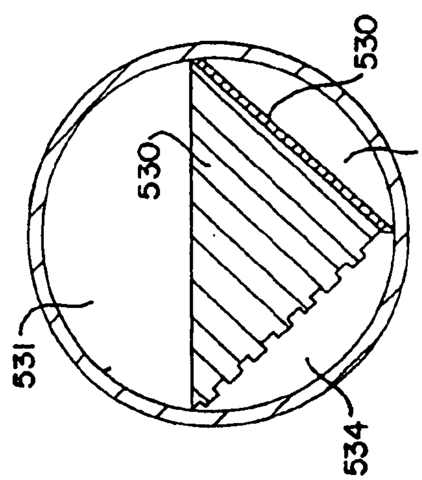


FIG. 12A

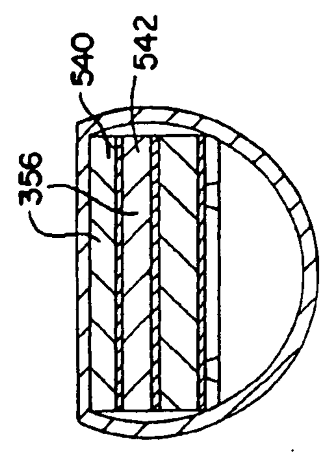


FIG. 11

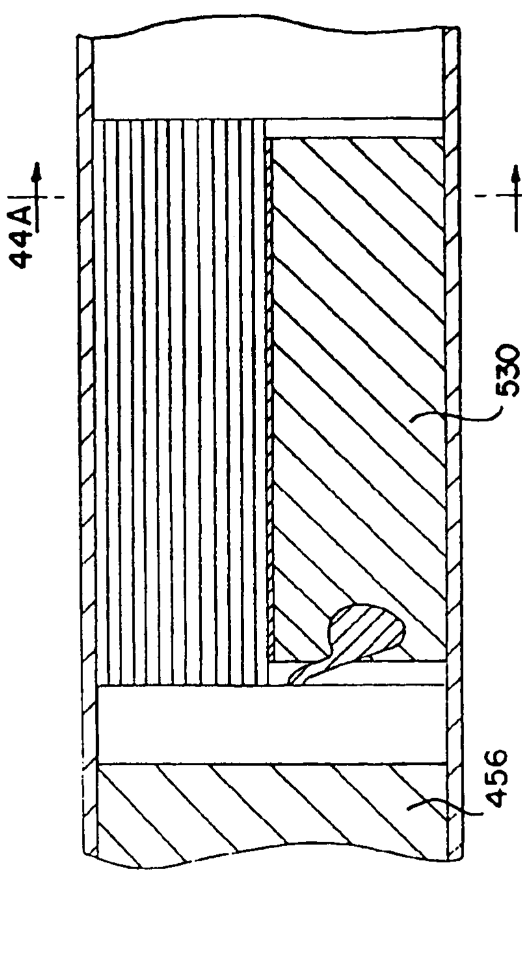
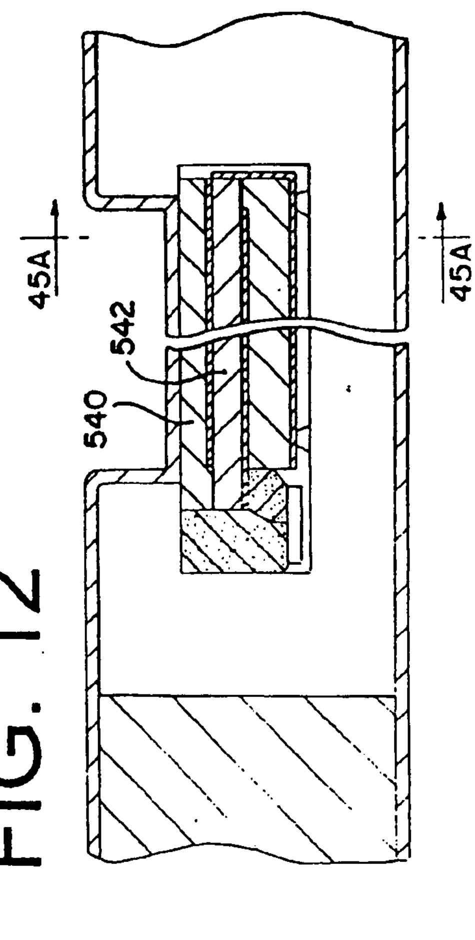


FIG. 12



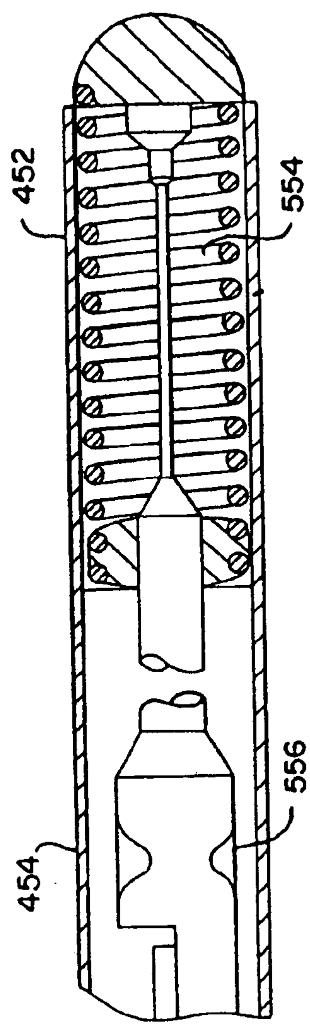


FIG. 13

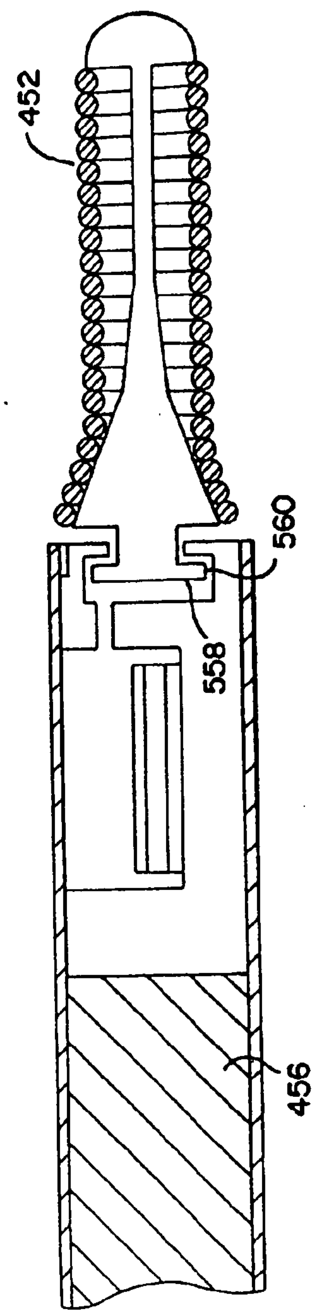


FIG. 14

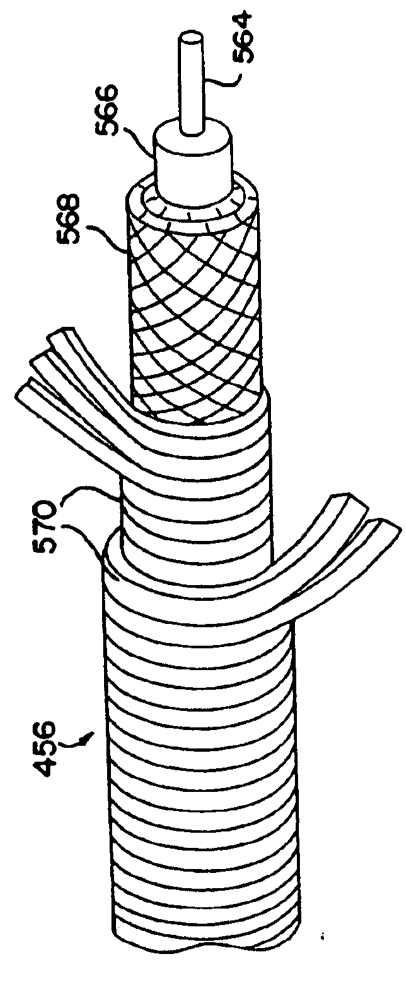


FIG. 15

FIG. 16

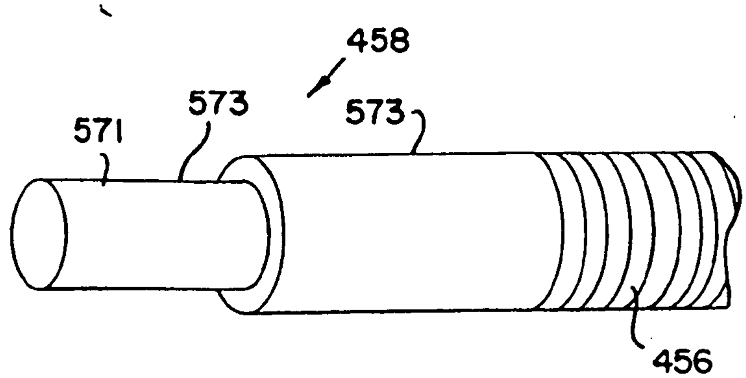


FIG. 17

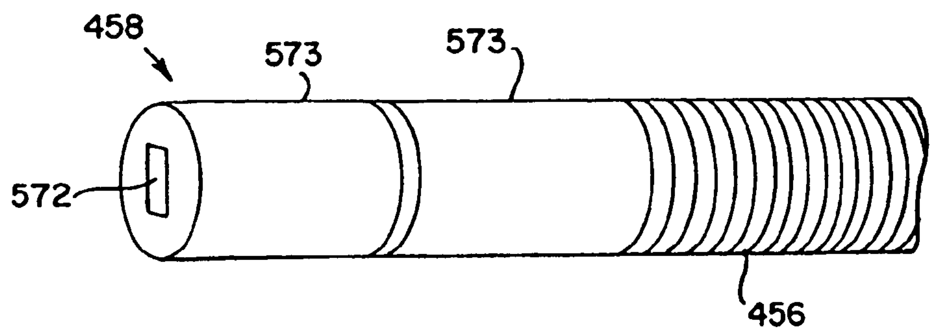


FIG. 18

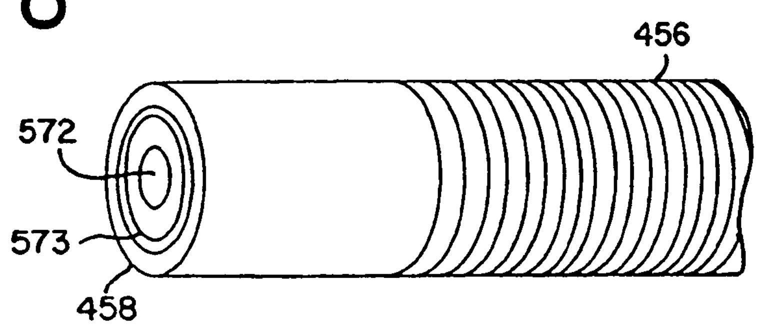


FIG. 19

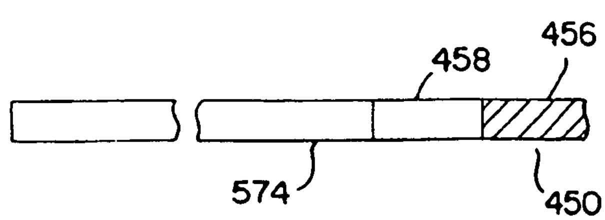


FIG. 21A

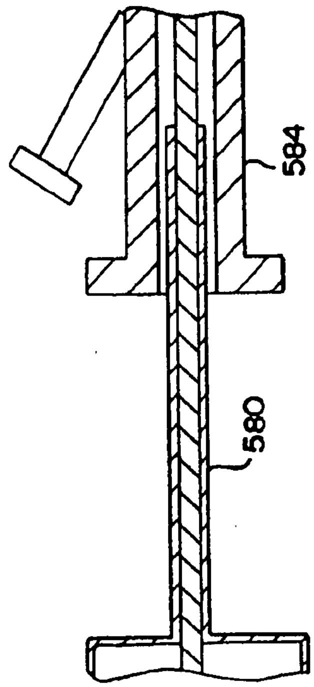


FIG. 21B

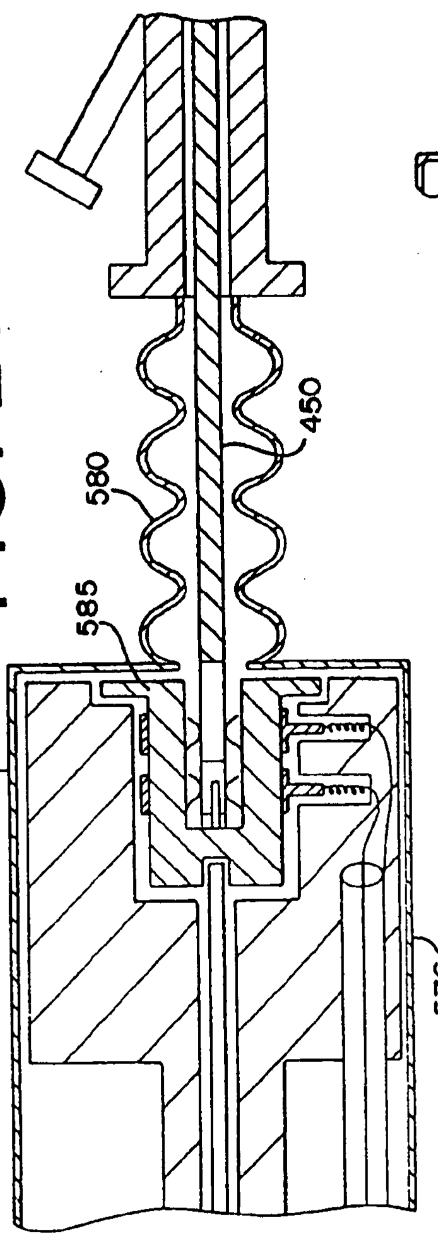


FIG. 20

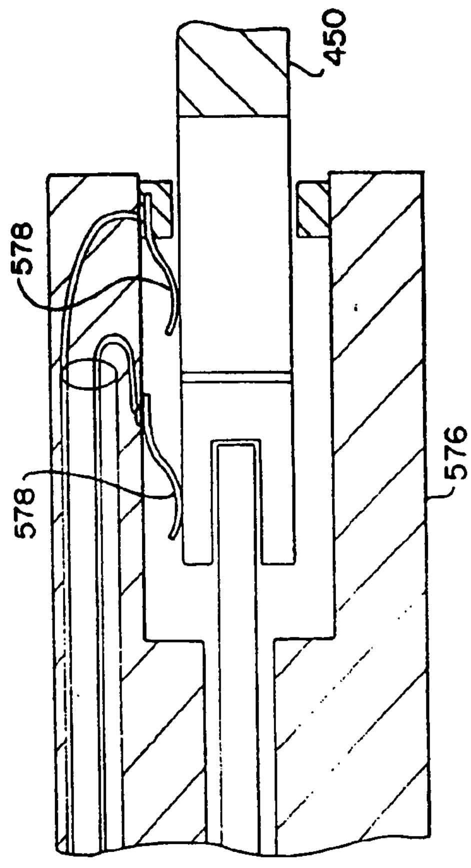


FIG. 22

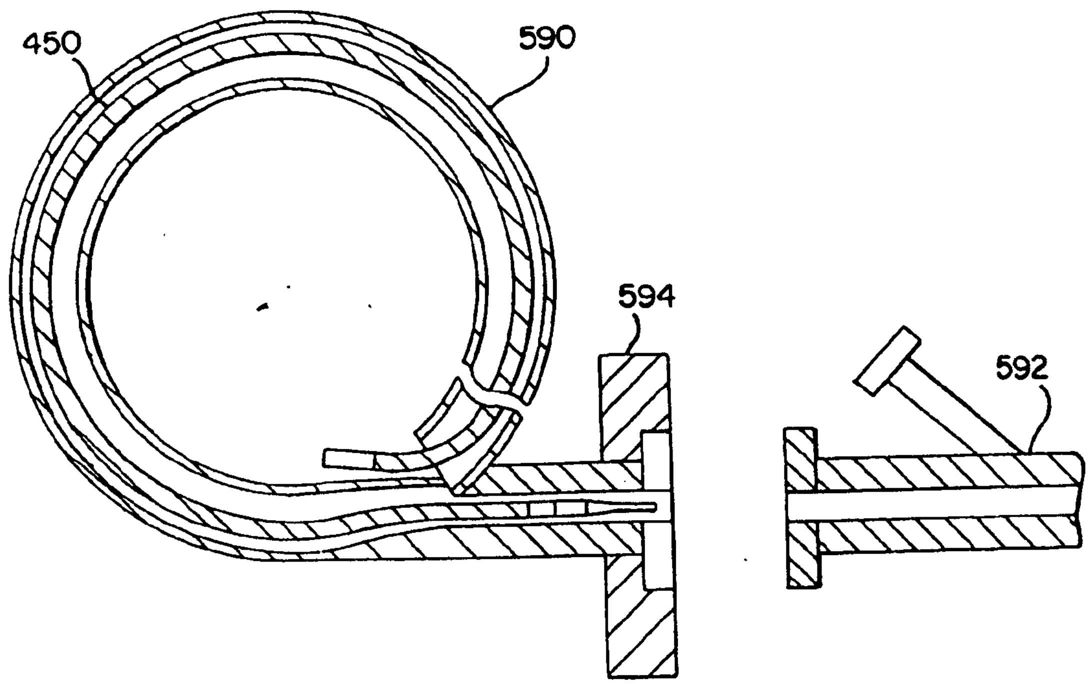


FIG. 24

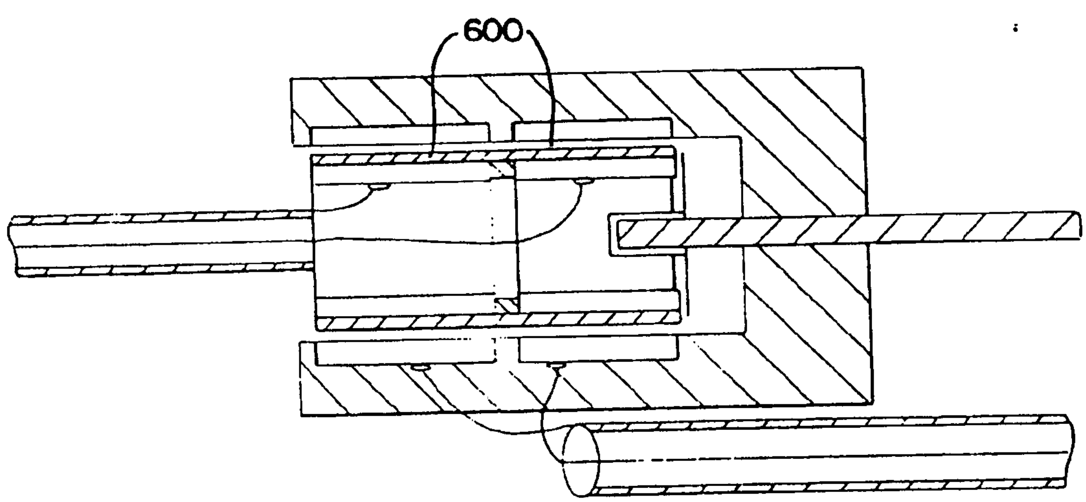


FIG. 23

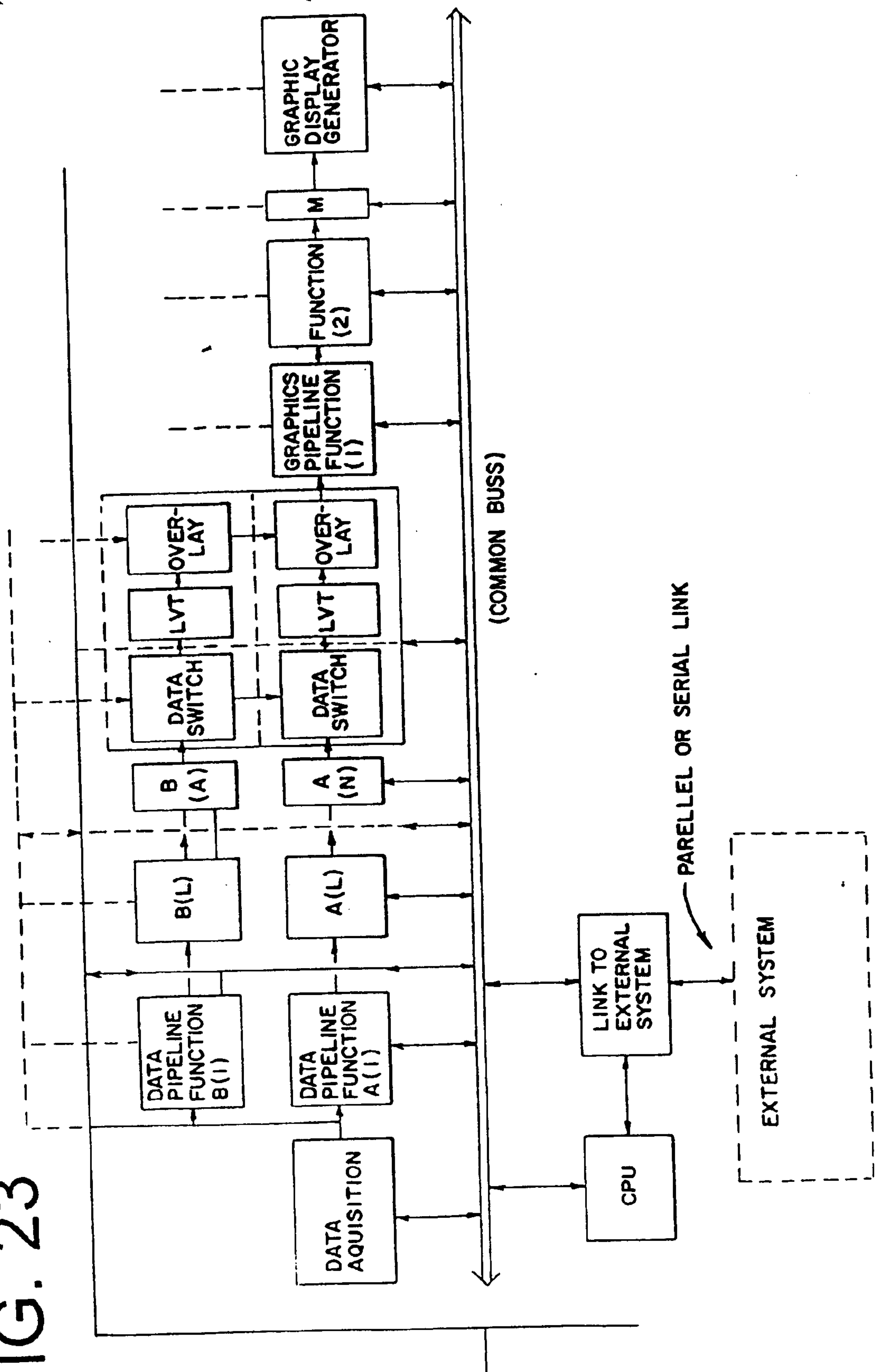

GRAPHIC DISPLAY GENERATOR
M
FUNCTION (2)
GRAPHICS PIPELINE FUNCTION (1)
OVER-LAY
LVT
DATA SWITCH
OVER-LAY
LVT
DATA SWITCH
B (A)
A (N)
B(L)
A(L)
DATA PIPELINE FUNCTION B(1)
DATA PIPELINE FUNCTION A(1)
DATA AQUISITION
(COMMON BUSS)
LINK TO EXTERNAL SYSTEM
CPU
PARELLEL OR SERIAL LINK
EXTERNAL SYSTEM

FIG. 25

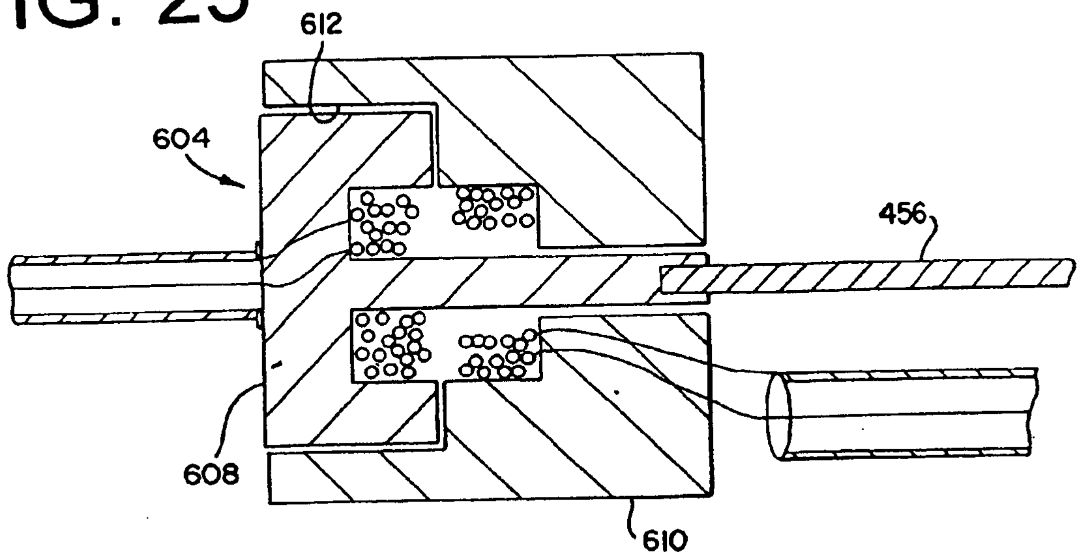


FIG. 26

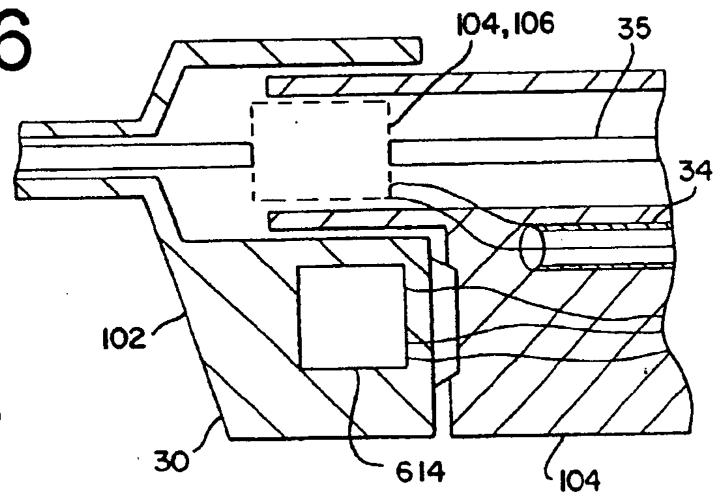
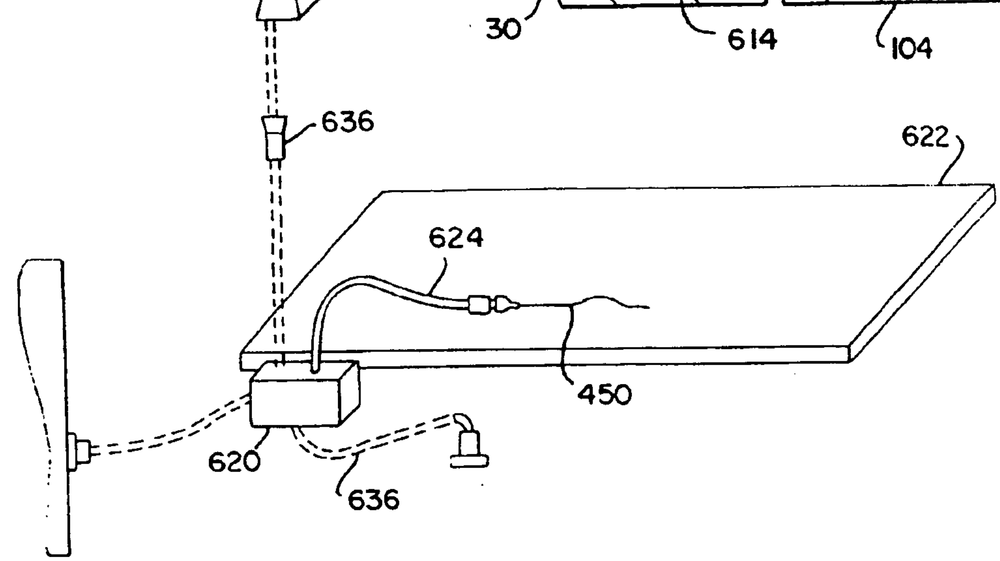


FIG. 27



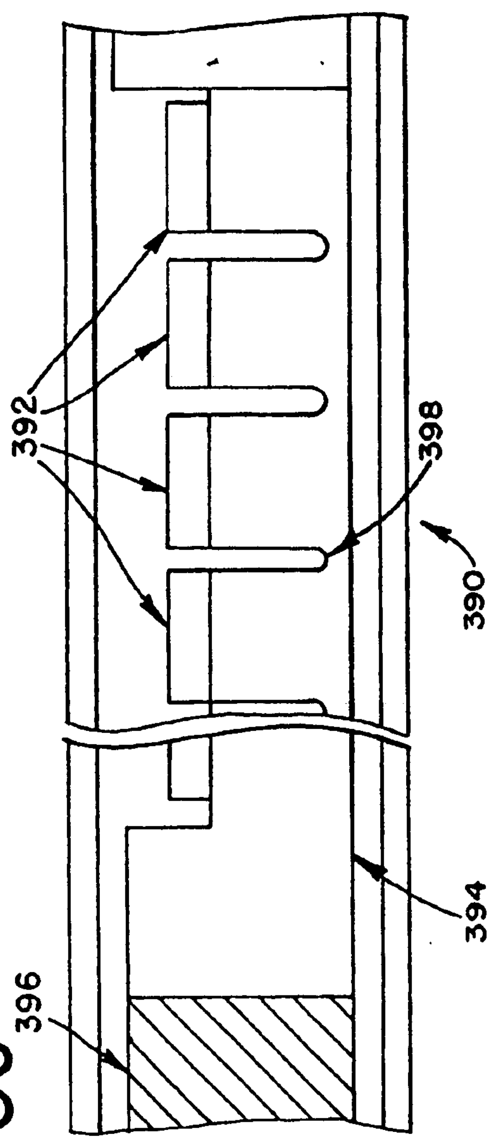


FIG. 30

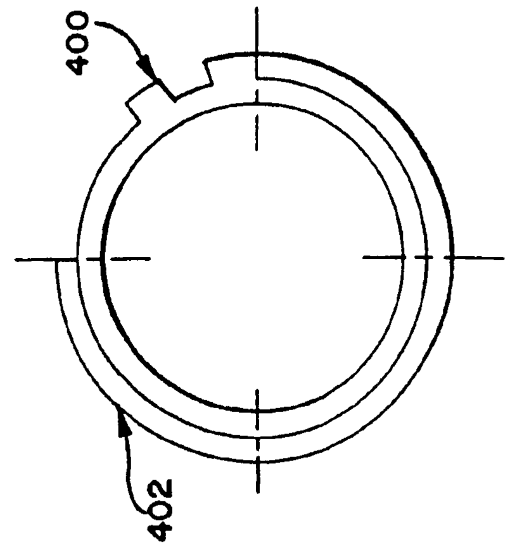


FIG. 32

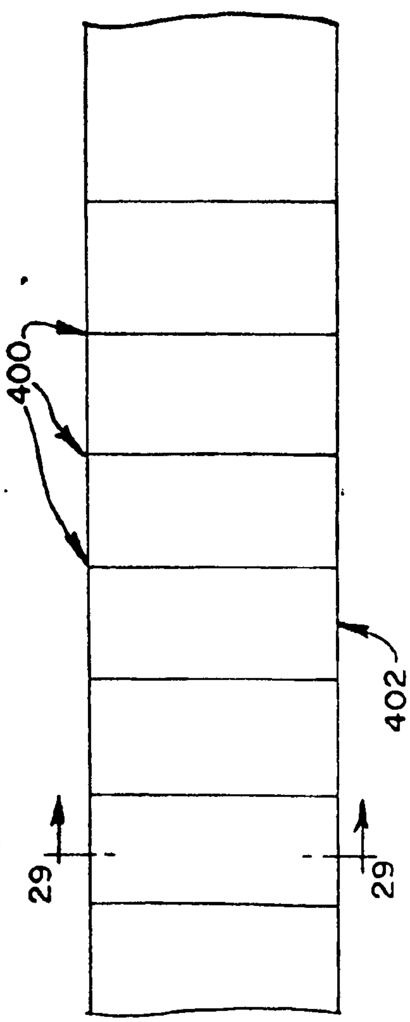


FIG. 31

FIG. 33

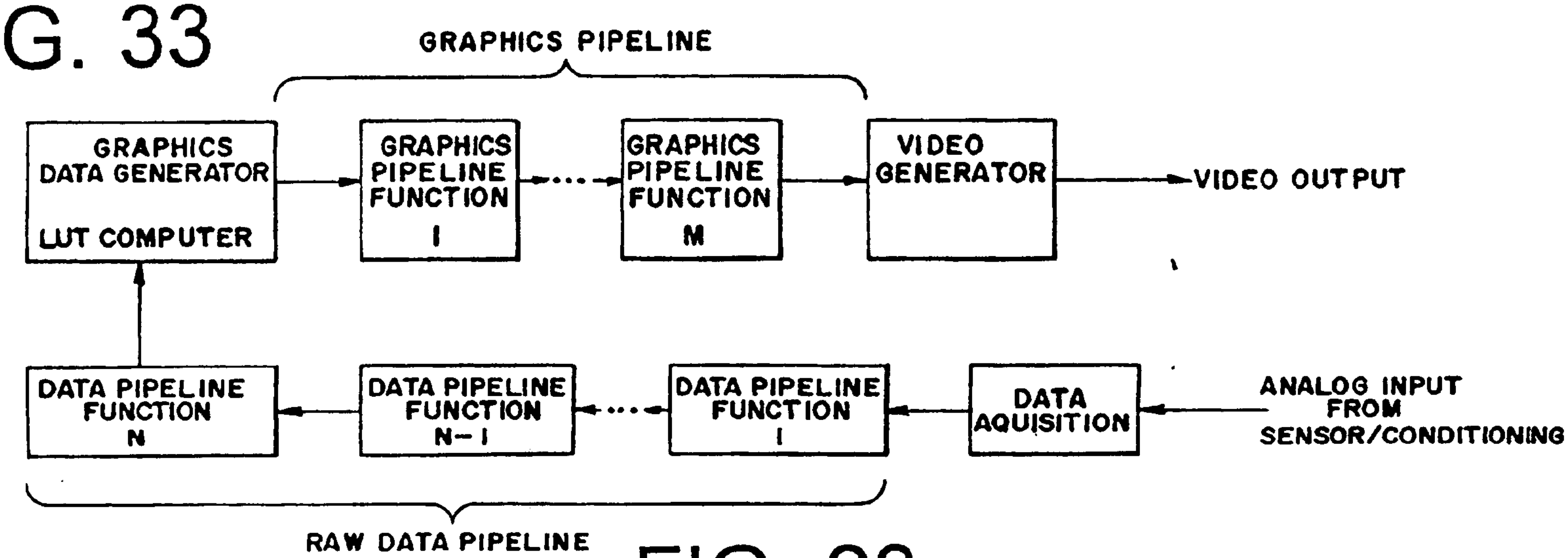


FIG. 28

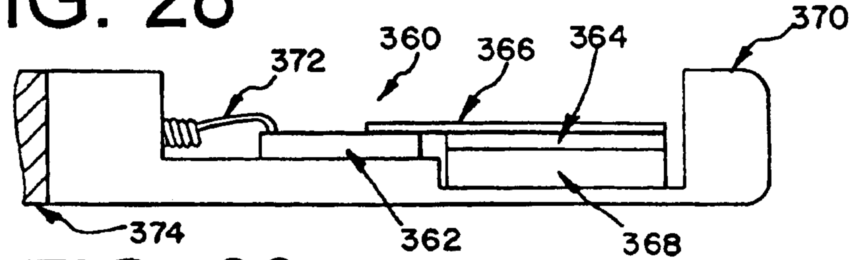


FIG. 29